

Exhibit 11

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 *****
5 IN RE: VALSARTAN, LOSARTAN, MDL No. 2875
6 AND IRBESARTAN PRODUCTS

7 LIABILITY LITIGATION Civil No.
8 19-2875

9 ***** (RBK/JS)

10 THIS DOCUMENT APPLIES TO ALL
11 CASES

HON ROBERT B.
KUGLER

12 *****

13 - CONFIDENTIAL INFORMATION -
14 SUBJECT TO PROTECTIVE ORDER

15

16

17

18 Remote Videotaped via Zoom
19 Deposition of JUCAI GE, held at the location
20 of the deponent, commencing at 7:04 a.m.
21 China Standard Time, on the 26th of May,
22 2022, before Maureen O'Connor Pollard,
23 Registered Diplomat Reporter, Realtime
24 Systems Administrator, Certified Shorthand
25 Reporter.

26

27

28

29 - - -
30 GOLKOW LITIGATION SERVICES
31 877.370.DEPS
32 deps@golkow.com

33

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1 REMOTE APPEARANCES:
 2
 3 MAZIE SLATER KATZ & FREEMAN, LLC
 4 BY: ADAM M. SLATER, ESQ.
 5 BY: CHRISTOPHER J. GEDDIS, ESQ.
 6 103 Eisenhower Parkway
 7 Roseland, New Jersey 07068
 8 973-228-9898
 9 aslater@mazieslater.com
 10 cgeddis@mazieslater.com
 11 Representing the Plaintiffs
 12
 13 MEYER WILSON CO., LPA
 14 BY: LAYNE HILTON, ESQ.
 15 900 Camp Street, Suite 337
 16 New Orleans, Louisiana 70130
 17 614-255-2697
 18 lhilton@meyerwilson.com
 19 Representing the Plaintiffs
 20
 21 HOLLIS LAW FIRM
 22 BY: IRIS SIMPSON, ESQ.
 23 8101 College Blvd., Suite 260
 24 Overland Park, Kansas 66210
 800-701-3672
 iris@hollislawfirm.com
 Representing the Plaintiffs
 FARR LAW FIRM
 BY: GEORGE T. WILLIAMSON, ESQ.
 99 Nesbit Street
 Punta Gorda, Florida 33950
 941-639-1158
 gwilliamson@farr.com
 Representing the Plaintiffs

Page 4

1 REMOTE APPEARANCES (Continued):
 2
 3 BARNES & THORNBURG, LLP
 4 BY: KARA KAPKE, ESQ.
 5 11 S. Meridian Street
 6 Indianapolis, Indiana 46204
 7 317-231-6491
 8 kara.kapke@btlaw.com
 9 Representing the Defendants CVS
 10 Pharmacy, Inc., and Rite Aid
 11 Corporation
 12
 13 GREENBERG TRAURIG, LLP
 14 BY: STEVEN M. HARKINS, ESQ.
 15 Terminus 200
 16 3333 Piedmont Road NE
 17 Suite 2500
 18 Atlanta, Georgia 30305
 19 678-553-2100
 20 harkinss@gtlaw.com
 21 Representing the Defendants Teva
 22 Pharmaceutical Industries, Ltd., Teva
 23 Pharmaceuticals SA, Inc., Actavis LLC,
 24 and Actavis Pharma, Inc.
 Interpreter: Dr. Yang Shao
 Check Interpreter: Phil Hughes
 Also Present:
 Stephanie Martin, Legal Assistant, Skadden
 Paget Houston, Summer Associate, Skadden
 Klara Bieniasz, Summer Associate, Skadden
 Videographer: Judy Diaz

Page 3

1 REMOTE APPEARANCES (Continued):
 2
 3 SKADDEN ARPS SLATE MEAGHER & FLOM LLP
 4 BY: RICHARD T. BERNARDO, ESQ.
 5 BY: ALLISON M. BROWN, ESQ.
 6 One Manhattan West
 7 New York, New York 10001-8602
 8 212-735-3453
 9 richard.bernardo@skadden.com
 10 allison.brown@skadden.com
 11 Representing the Defendants Zhejiang
 12 Huahai Pharmaceutical Co., Ltd.,
 13 Princeton Pharmaceutical Inc., Huahai
 14 U.S., Inc., and Solco Healthcare US,
 15 LLC
 16
 17 SKADDEN ARPS SLATE MEAGHER & FLOM LLP
 18 BY: CATHERINE I. MULLALEY, ESQ.
 19 500 Boylston Street
 20 Boston, Massachusetts 02116
 21 617-573-4851
 22 kate.mullaley@skadden.com
 23 Representing the Defendants Zhejiang
 24 Huahai Pharmaceutical Co., Ltd.,
 Princeton Pharmaceutical Inc., Huahai
 U.S., Inc., and Solco Healthcare US,
 LLC
 PIETRAGALLO GORDON ALFANO BOSICK &
 RASPANTI, LLP
 BY: FRANK H. STOY, ESQ.
 One Oxford Centre
 Pittsburgh, Pennsylvania 15219
 412-263-1840
 fhs@pietragallos.com
 Representing the Defendant, Mylan
 Pharmaceuticals, Inc.

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<div> <div>Page 7</div> <div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>11</div> <div>12</div> <div>13</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> </div> <div> <p>- - - DEPOSITION SUPPORT INDEX - - -</p> <p>Direction to Witness Not to Answer PAGE LINE 19 22</p> <p>Request for Production of Documents PAGE LINE None.</p> <p>Stipulations PAGE LINE None.</p> <p>Questions Marked Highly Confidential PAGE LINE None.</p> </div> </div>	<div> <div>Page 9</div> <div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>11</div> <div>12</div> <div>13</div> <div>14</div> <div>15</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> </div> <div> <p>interpreter and the witness.</p> <p>- - - YANG SHAO, Interpreter, having been duly remotely sworn to translate the questions and answers to the best of his ability, translated as follows:</p> <p>- - - JUCAI GE, having been duly remotely identified and sworn, was examined and testified as follows through the interpreter:</p> <p>EXAMINATION</p> <p>BY MR. SLATER:</p> <p>Q. Good evening.</p> <p>A. Good evening.</p> <p>Q. I guess it's good morning for you.</p> <p>A. That's correct. It is morning here.</p> <p>Q. We're going to take your deposition now. You know that, right?</p> <p>A. I understand that.</p> <p>Also, I'd like to express my appreciation to Adam for postponing this</p> </div> </div>

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1 deposition by a month. Originally I was
2 supposed to be quarantined for a month. So
3 thank you for your understanding.
4 Q. You're welcome. I've never
5 been thanked by a witness before. This is
6 the best night of my life.
7 A. Thank you.
8 Q. I hope that you'll thank me at
9 the end also.
10 A. I hope so, too. I will do my
11 best to work with you.
12 Q. You understand as you just --
13 rephrase.
14 You just took an oath to tell
15 the truth. You understand you must be
16 truthful in answering all questions in this
17 deposition, correct?
18 A. That is correct. That is for
19 sure.
20 MR. SLATER: Chris, let's put
21 up the deposition notice, please.
22 (Whereupon, ZHP Exhibit Numbers
23 456A and 456B were marked for
24 identification.)

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1 BY MR. SLATER:
2 Q. This is the deposition notice
3 for today's deposition.
4 Have you seen this document?
5 A. Yes, I've seen it before.
6 MR. SLATER: Let's go to
7 Exhibit Number 2, the response to the
8 deposition notice.
9 BY MR. SLATER:
10 Q. Have you seen this document,
11 the response to the deposition notice?
12 A. I've also seen this before.
13 MR. SLATER: We can take that
14 down.
15 MR. GEDDIS: Adam, just for the
16 record, it's -- Exhibit 456A is the
17 English dep notice; 456B is the
18 Chinese translation, and then
19 obviously so on for the next document.
20 MR. SLATER: Okay. So the
21 second exhibit is 457A and 457B?
22 MR. GEDDIS: Yes.
23 MR. BERNARDO: Oh, I'm sorry.
24 So the system is that each English

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1 version is the A and each Chinese
2 version is the B, and they get the
3 same number?
4 MR. GEDDIS: Yeah, that's what
5 we've been doing in the past.
6 MR. BERNARDO: Thank you.
7 BY MR. SLATER:
8 Q. Did you prepare to testify in
9 this deposition?
10 A. That is correct. I've done a
11 lot of work in preparation for today's
12 deposition in order to answer the related
13 questions.
14 Q. Can you estimate how much time
15 you spent preparing?
16 A. It was sometime in March that I
17 received the deposition notice that I would
18 testify as the representative of the company
19 on certain topics, so I spent a lot of time
20 to be familiar with all those topics.
21 And also I would communicate
22 with people and review related documents.
23 Every day I would spend from six to ten hours
24 doing that, except for the two days I spent

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1 on my way here.
2 Therefore, every day I have
3 been spending six to ten hours a day to be
4 familiar with the topics and to communicate
5 with people.
6 Q. And that is since March, when
7 you first were told about the deposition?
8 A. Essentially, yes.
9 Q. Do you know what day in March
10 that was, approximately or exactly?
11 A. I do not recall the exact date.
12 All I can recall is that it was sometime
13 before the Chinese Memorial Day. After that,
14 I've been very busy reviewing the documents
15 and communicating with people.
16 Q. What day is Chinese Memorial
17 Day?
18 A. April 5th.
19 Q. We were advised that you
20 interviewed a number of people to help you
21 prepare, is that correct?
22 A. I don't quite get your
23 question. However, once I was notified that
24 I would represent the company to attend this

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1 deposition, I first approached my attorney or
2 attorneys to have a better understanding of
3 the topics. Then I approached related people
4 and communicated with them, and I also
5 reviewed the related documents.
6 Q. As part of your preparation,
7 did you speak with Min Li? Yes or no.
8 A. Yes, I did.
9 Q. As part of your preparation,
10 did you speak with Jinsheng Lin?
11 A. Yes, I did.
12 Q. As part of your preparation,
13 did you speak with Peng Dong?
14 A. Yes, I did.
15 Q. As part of your preparation,
16 did you speak with Linda Lin?
17 A. Yes, I did.
18 Q. As part of your preparation,
19 did you speak with Hai Wang?
20 A. Yes, I did.
21 Q. As part of your preparation,
22 did you speak with Lewis Chodosh?
23 A. Yes, I did.
24 Q. Did you speak with anybody else

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1 to help you prepare for this deposition?
2 MR. BERNARDO: Object to the
3 form of the question.
4 THE WITNESS: Are you referring
5 to the preparation for this deposition
6 in general without being specific for
7 any topic?
8 BY MR. SLATER:
9 Q. I don't understand your
10 question.
11 A. As for the people you just
12 mentioned, I mainly communicate with them.
13 Q. Is there anybody else that you
14 spoke with to help you prepare to testify in
15 this deposition?
16 A. When it comes to issues like
17 English, I did communicate with people from
18 the QA department.
19 I also communicated with people
20 such as Wei Cheng, spelled as W-E-I, last
21 name C-H-E-N-G, on topics like responses.
22 Q. When you say you spoke with
23 people in the QA department regarding
24 English, what do you mean by that?

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1 A. Because I'm poor in English,
2 and many documents, on the other hand, are in
3 English. So I approached the people in the
4 QA department and asked them to help me
5 translate. They had to help me find related
6 documents and then do the translation. That
7 is because, indeed, my English is really
8 poor.
9 Q. When did you speak to Lewis
10 Chodosh?
11 Let me reask the question.
12 When did you speak with Lewis Chodosh?
13 A. I don't recall the exact time.
14 However, since he is based in the US, we were
15 scheduled to have a meeting on a certain
16 evening.
17 Q. Why did you speak to Lewis
18 Chodosh?
19 A. That was because I read a
20 report of the impact of NDMA or NDEA on
21 health written by Dr. Chodosh, so I wanted to
22 communicate with him regarding that report.
23 MR. SLATER: Chris, let's mark
24 the -- put up the binder, and you can

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1 let us know what exhibit number it is.
2 MR. GEDDIS: It's Exhibit 458.
3 I'll open it in one second.
4 (Whereupon, Exhibit Numbers
5 ZHP-458A and ZHP- 458B were marked for
6 identification.)
7 MR. GEDDIS: Do you want it in
8 Chinese or English on the screen?
9 MR. SLATER: You know, I just
10 really want the first page, just so we
11 can identify it. The English is fine.
12 BY MR. SLATER:
13 Q. This is Exhibit 458A, and it's
14 the table of contents for a binder we were
15 provided.
16 Is that a binder that you
17 reviewed?
18 A. Not only did I review all the
19 documents listed here; I also reviewed other
20 documents, simply because these documents are
21 quite related to this case. I list those
22 documents here.
23 Q. Did you compile the binder
24 yourself?

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1 A. I compiled the Chinese version
2 of the documents, and I got help for the
3 translation for the English version, because
4 I did not do the translation myself. I only
5 compiled the Chinese version of the
6 documents.
7 Q. Item 3 is the Chodosh report
8 and supplement. Did you have that in your
9 possession, or did somebody give that to you?
10 A. I don't quite understand your
11 question. Can you be more specific?
12 Q. Who gave you the Chodosh report
13 and supplement?
14 A. Oh, now I understand your
15 question.
16 That was during the discussion
17 of the topics. My attorney or attorneys
18 mentioned the evaluation report by
19 Dr. Chodosh; therefore, I asked my attorney
20 or attorneys to arrange for the delivery of
21 such report to me.
22 Q. Item 4 is the Bottorff report.
23 Why did you read that?
24 A. Likewise, during the

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1 discussion, the attorneys not only mentioned
2 the report by Dr. Chodosh, but also this
3 report. I, therefore, wanted to find out
4 what is in such a report. Therefore, I asked
5 the attorneys to have that report delivered
6 to me.
7 Q. Item 5 is the Wang report. Why
8 did you read that?
9 A. The reason why I reviewed the
10 Wang report was because during my
11 communication with Min Li, spelled as M-I-N,
12 last name L-I, he mentioned that Dr. Wang at
13 the early stage did a preliminary
14 investigation and generated a report.
15 I also wanted to find out the
16 content of this report. Likewise, I asked my
17 attorneys to have that report delivered to
18 me.
19 Q. Were you told anything about a
20 toxicologist named Janice Britt?
21 MR. BERNARDO: Object to the
22 form of the question, and direct the
23 witness not to answer to the extent
24 that she was told anything by counsel.

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1 But otherwise you can answer.
2 MR. SLATER: Let me ask it
3 differently. New question.
4 BY MR. SLATER:
5 Q. In your preparation, did you
6 learn of the existence of a toxicologist
7 named Janice Britt?
8 A. No, I didn't.
9 Q. During your preparation, were
10 you made aware of someone named Dipak
11 Panigrahy?
12 MR. BERNARDO: Object to the
13 form of the question. Same objection.
14 Adam, you refer to last name
15 with the rephraseology.
16 BY MR. SLATER:
17 Q. As part of your preparation,
18 did you learn of the existence of a doctor
19 named Dipak, D-I-P-A-K, Panigrahy,
20 P-A-N-I-G-R-A-H-Y?
21 A. I don't know of this person.
22 Q. During your preparation, did
23 you become aware of the existence of
24 Dr. Stephen Lagana?

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1 A. Not for this person. I don't
2 know of this person.
3 Q. During your preparation, did
4 you become aware of the existence of
5 Dr. Steven Hecht?
6 A. No, I never saw this name
7 before.
8 Q. During your preparation, did
9 you become aware of the existence of
10 Dr. Etminan?
11 A. I don't believe I know this
12 person.
13 As for all the people you just
14 mentioned, since they all bear the English
15 names, even had I seen those names in my
16 review of the documents, I would have skipped
17 those names; therefore, I would not have any
18 recollection of those names. I don't know
19 any of them.
20 Q. During your preparation, did
21 you become aware of the existence of
22 Dr. Madigan?
23 A. Seems like I don't have any
24 impression.

<p>Page 22</p> <p>1 Q. As part of your preparation,</p> <p>2 did you read the transcripts of the</p> <p>3 depositions of Min Li, Peng Dong, Linda Lin,</p> <p>4 or Hai Wang?</p> <p>5 A. Only excerpts. Only a very</p> <p>6 short excerpt. I didn't read much.</p> <p>7 Q. Did you ever read your own</p> <p>8 deposition transcript?</p> <p>9 A. Yes, I did.</p> <p>10 Q. Did you take notes when you</p> <p>11 prepared for this deposition?</p> <p>12 A. No, I didn't take any notes.</p> <p>13 Q. Do you know what excerpts you</p> <p>14 looked at from the depositions of Min Li,</p> <p>15 Peng Dong, Linda Lin, and Hai Wang?</p> <p>16 A. I don't recall, because the</p> <p>17 excerpt was quite short and didn't say much.</p> <p>18 And I took a quick look and didn't find any</p> <p>19 issue, so I do not recall what it said.</p> <p>20 Q. Did you select the excerpts to</p> <p>21 review, or did somebody else select the</p> <p>22 excerpts for you?</p> <p>23 A. Likewise, it was during the</p> <p>24 discussion on the topics, the attorneys</p>	<p>Page 23</p> <p>1 mentioned those transcripts that might be</p> <p>2 relating to those topics, so I asked the</p> <p>3 attorneys to provide some excerpts for me to</p> <p>4 review.</p> <p>5 However, since those excerpts</p> <p>6 are in English, and I don't read English, the</p> <p>7 workload to translate those excerpts was too</p> <p>8 high, so I only read a small portion of those</p> <p>9 excerpts, maybe a part of Peng Dong's</p> <p>10 deposition transcript, and I didn't find that</p> <p>11 very useful.</p> <p>12 Instead, I found that oral</p> <p>13 communication with those people would be more</p> <p>14 helpful and would give me more information;</p> <p>15 therefore, I didn't read much of those</p> <p>16 excerpts.</p> <p>17 Q. Did somebody translate the</p> <p>18 excerpts that you did read?</p> <p>19 A. That is correct.</p> <p>20 Q. Who?</p> <p>21 A. For some of those, as I just</p> <p>22 stated in my prior testimony, I asked a</p> <p>23 person called Wei Cheng, W-E-I, last name</p> <p>24 C-H-E-N-G, from the QA department to help me.</p>	<p>Page 24</p> <p>1 Q. Item 6 on this list is 1978</p> <p>2 IARC monograph excerpts. Is that 1978 IARC</p> <p>3 monograph found in the files of ZHP?</p> <p>4 A. I don't quite get your</p> <p>5 question. However, likewise, I received this</p> <p>6 document through my attorneys, and I also got</p> <p>7 help for the Chinese translation.</p> <p>8 The original monograph was a</p> <p>9 thick book in English, so I only had the</p> <p>10 excerpt, the comment part, translated into</p> <p>11 Chinese for me to review.</p> <p>12 Q. Item 8 is Gomm, G-O-M-M, et al.</p> <p>13 It's a medical article.</p> <p>14 Did you read that?</p> <p>15 A. Yes, I did.</p> <p>16 Q. Why?</p> <p>17 A. That was because this article</p> <p>18 also commented on the impact of NDMA in</p> <p>19 valsartan on health. That's why I asked them</p> <p>20 to provide this document to me for review.</p> <p>21 Q. When you say it commented on</p> <p>22 the impact of NDMA on health, did that</p> <p>23 include the statistically significant finding</p> <p>24 of a causal relationship between the NDMA in</p>	<p>Page 25</p> <p>1 the valsartan pills and liver cancer?</p> <p>2 MR. BERNARDO: Object to the</p> <p>3 form of the question.</p> <p>4 THE WITNESS: I did review the</p> <p>5 content, and also reviewed the</p> <p>6 conclusion.</p> <p>7 As for the specifics, you had</p> <p>8 better just show it to me so that we</p> <p>9 can have a better discussion.</p> <p>10 However, I do have some</p> <p>11 recollection, even though the</p> <p>12 recollection is not quite clear.</p> <p>13 I did remember that in</p> <p>14 conclusion, the risk that NDMA caused</p> <p>15 to human health was not existing.</p> <p>16 At the end of the article, it</p> <p>17 did mention and list certain issues</p> <p>18 and listed out some factors of</p> <p>19 uncertainty, but as the conclusion,</p> <p>20 the article did say that NDMA did not</p> <p>21 cause any risk to human health.</p> <p>22 If you want to have a detailed</p> <p>23 discussion regarding the content, we'd</p> <p>24 better just take a look at this</p>
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<p>Page 26</p> <p>1 article.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. That was your understanding of</p> <p>4 the conclusion of the article, what you just</p> <p>5 told me?</p> <p>6 A. Well, that is correct.</p> <p>7 Q. You're not a toxicologist,</p> <p>8 right?</p> <p>9 A. That is correct. I am not.</p> <p>10 MR. SLATER: All right. Chris,</p> <p>11 let's put up the FDA warning letter</p> <p>12 previously marked as Exhibit 213.</p> <p>13 (Whereupon, Exhibit Number</p> <p>14 ZHP-213A and ZHP-213B were previously</p> <p>15 marked for identification.)</p> <p>16 THE WITNESS: I see it.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Halfway down the first page is</p> <p>19 a paragraph that says -- rephrase. I'm going</p> <p>20 to start over.</p> <p>21 The third paragraph of the FDA</p> <p>22 warning letter says -- rephrase. I'm going</p> <p>23 to ask it again.</p> <p>24 The third paragraph states,</p>	<p>Page 28</p> <p>1 "adulterated" means.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. What does "adulterated" mean?</p> <p>4 A. In terms of the meaning of</p> <p>5 being adulterated with the aforementioned</p> <p>6 501(a)(2)(B), there was a definition for the</p> <p>7 meaning.</p> <p>8 Q. You said you understand what</p> <p>9 "adulterated" means. Tell me your</p> <p>10 understanding of the definition.</p> <p>11 A. As for the understanding of the</p> <p>12 word "adulterated," I understand its meaning.</p> <p>13 It's actually a terminology only used by FDA.</p> <p>14 Typically we as enterprises do not use this</p> <p>15 term.</p> <p>16 If you want an exact definition</p> <p>17 of this term, then you have to resort to</p> <p>18 Section 501(a)(2)(B).</p> <p>19 But I understand what it means.</p> <p>20 That means that in our manufacturing process,</p> <p>21 our methods, facilities, and controls did not</p> <p>22 conform to the cGMP. That's what it means.</p> <p>23 However, this term also has a</p> <p>24 time limit, and only FDA defines this term.</p>
<p>Page 27</p> <p>1 "Because your methods, facilities, or</p> <p>2 controls for manufacturing, processing,</p> <p>3 packing, or holding do not conform to CGMP,</p> <p>4 your API are adulterated within the meaning</p> <p>5 of section 501(a)(2)(B) of the Federal Food,</p> <p>6 Drug, and Cosmetic Act, 21 U.S.C.,</p> <p>7 351(a)(2)(B)."</p> <p>8 Do you understand what</p> <p>9 "adulterated" means?</p> <p>10 MR. BERNARDO: Object to the.</p> <p>11 THE WITNESS: Dr. Shao, I quite</p> <p>12 understand -- I don't quite get the</p> <p>13 Chinese translation of this paragraph.</p> <p>14 INTERPRETER SHAO: The</p> <p>15 interpreter would like to repeat the</p> <p>16 rendition.</p> <p>17 MR. SLATER: Okay.</p> <p>18 THE WITNESS: Maybe something</p> <p>19 is lost in the Chinese translation, so</p> <p>20 I still don't quite get the</p> <p>21 translation of this paragraph.</p> <p>22 However, with this paragraph, I</p> <p>23 still have the recollection of FDA's</p> <p>24 conclusion, and I also understand what</p>	<p>Page 29</p> <p>1 I'm sorry, Dr. Shao. Maybe I</p> <p>2 didn't make myself very clear. What I said</p> <p>3 was, only FDA would use this term in their</p> <p>4 conclusion, and they also use such terms for</p> <p>5 their FDA approvals.</p> <p>6 Q. You don't work in the</p> <p>7 regulatory department, do you?</p> <p>8 A. That is correct, I do not work</p> <p>9 in the regulatory department. Instead, I</p> <p>10 work in the QA department.</p> <p>11 Q. Who told you what "adulterated"</p> <p>12 means?</p> <p>13 A. First of all, this term</p> <p>14 "adulterate" has something to do with GMP,</p> <p>15 and I would engage GMP in my daily work.</p> <p>16 Secondly, for this term, I also</p> <p>17 consulted with Linda from the RA department</p> <p>18 and had a discussion with her about the</p> <p>19 meaning.</p> <p>20 Q. And you under- -- rephrase.</p> <p>21 And you understand that when</p> <p>22 the FDA made its finding of adulteration, its</p> <p>23 finding was based on violations of cGMP by</p> <p>24 ZHP in the manufacturing process for the</p>

<p style="text-align: right;">Page 30</p> <p>1 valsartan, correct?</p> <p>2 MR. BERNARDO: Object to the</p> <p>3 form of the question.</p> <p>4 THE WITNESS: I don't quite get</p> <p>5 your question. Can the interpreter</p> <p>6 repeat the rendition?</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Sure.</p> <p>9 A. I'm sorry. Something must have</p> <p>10 lost in the translation, so I don't quite get</p> <p>11 your question. However, I will do my best to</p> <p>12 respond to it.</p> <p>13 As I stated in my prior</p> <p>14 statement, "adulteration" is a term that FDA</p> <p>15 would use. In their finding, they found</p> <p>16 there was some deviation there, that we</p> <p>17 actually did not conform to GMP.</p> <p>18 Of course, it was within the</p> <p>19 scope of FDA's authority to make such a</p> <p>20 finding. However, from our company's point</p> <p>21 of view, we have always been conformed to GMP</p> <p>22 or in compliance with GMP. That position has</p> <p>23 been reflected in our response to FDA's</p> <p>24 warning letter, as well as the communications</p>	<p style="text-align: right;">Page 32</p> <p>1 been in compliance with the cGMP, in</p> <p>2 order to work with FDA and the</p> <p>3 response to this finding, we did a lot</p> <p>4 of work for improvement seriously and</p> <p>5 diligently.</p> <p>6 Secondly, our company is a</p> <p>7 responsible company. Ever since we</p> <p>8 received this warning letter, we</p> <p>9 stopped the sales in the US.</p> <p>10 I don't know whether I got the</p> <p>11 key point of your question and</p> <p>12 answered your question, but I will try</p> <p>13 my best to answer this question.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. In the FDA warning letter, the</p> <p>16 FDA says on the first page, "During our</p> <p>17 inspection, our investigators observed</p> <p>18 specific deviations including, but not</p> <p>19 limited to, the following.</p> <p>20 "Number 1. Failure of your</p> <p>21 quality unit to ensure that quality-related</p> <p>22 complaints are investigated and resolved."</p> <p>23 Later in the letter, "Number 2.</p> <p>24 Failure to evaluate the potential effect that</p>
<p style="text-align: right;">Page 31</p> <p>1 with FDA over a long period of time.</p> <p>2 I'm not sure whether your</p> <p>3 question is answered.</p> <p>4 Q. So you're telling me ZHP has</p> <p>5 never taken responsibility for its violations</p> <p>6 of cGMP?</p> <p>7 MR. BERNARDO: Object to the</p> <p>8 form of the question.</p> <p>9 THE WITNESS: I don't know</p> <p>10 whether it's because I'm from a</p> <p>11 different profession, I couldn't</p> <p>12 understand your question. After all,</p> <p>13 I'm not a lawyer. However, I will do</p> <p>14 my best to answer your question as</p> <p>15 follows.</p> <p>16 First, after their discovery,</p> <p>17 FDA did gave us the warning letter</p> <p>18 stating that ZHP failed to conform to</p> <p>19 cGMP. However, from the company's</p> <p>20 point of view, we have been in</p> <p>21 compliance with the cGMP, which was</p> <p>22 also reflected in our response to the</p> <p>23 warning letter.</p> <p>24 Even though the company has</p>	<p style="text-align: right;">Page 33</p> <p>1 changes in the manufacturing process may have</p> <p>2 on the quality of your API."</p> <p>3 You're aware that the FDA found</p> <p>4 both of those deviations and put them in the</p> <p>5 warning letter, correct?</p> <p>6 MR. BERNARDO: Object to the</p> <p>7 form of the question.</p> <p>8 THE WITNESS: I believe it</p> <p>9 should be put in this way. In the</p> <p>10 warning letter, FDA did put two</p> <p>11 deviations that they thought were</p> <p>12 deviations in the letter.</p> <p>13 First, the investigation of --</p> <p>14 on the complaints were not sufficient.</p> <p>15 Secondly, the deviation</p> <p>16 regarding the evaluation of the</p> <p>17 potential effect from the changes.</p> <p>18 Indeed, they put those two</p> <p>19 deviations in the warning letter.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. The FDA also rejected ZHP's</p> <p>22 explanation and argument that it had not</p> <p>23 committed these deviations, correct?</p> <p>24 MR. BERNARDO: Object to the</p>

<p style="text-align: right;">Page 34</p> <p>1 form of the question.</p> <p>2 THE WITNESS: I wonder where I</p> <p>3 can find such statement that you just</p> <p>4 made or referred to in this warning</p> <p>5 letter. I failed to find such</p> <p>6 statements in the letter.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Let's go to page 4. The third</p> <p>9 paragraph under -- I'm sorry.</p> <p>10 On page 4, the third paragraph</p> <p>11 under number 2 says, "Your response states</p> <p>12 that predicting NDMA formation during the</p> <p>13 valsartan manufacturing process required an</p> <p>14 extra dimension over current industry</p> <p>15 practice, and that your process development</p> <p>16 study was adequate. We disagree. We remind</p> <p>17 you that common industry practice may not</p> <p>18 always be consistent with CGMP requirements</p> <p>19 and that you are responsible for the quality</p> <p>20 of drugs you produce."</p> <p>21 Does that refresh your memory</p> <p>22 the FDA said in rejecting ZHP's response to</p> <p>23 the findings of deviations?</p> <p>24 MR. BERNARDO: Object to the</p>	<p style="text-align: right;">Page 36</p> <p>1 where the presence of NDMA was suspected to</p> <p>2 elute. At the time of testing, you</p> <p>3 considered this unidentified peak to be noise</p> <p>4 and investigated no further. Additionally,</p> <p>5 residual solvent chromatograms for valsartan</p> <p>6 API validation batches manufactured using</p> <p>7 your zinc chloride process, with DMF in 2012</p> <p>8 (C5355-12-001, C5355-12-002, and</p> <p>9 C5355-12-003) show at least one unidentified</p> <p>10 peak eluting after the toluene peak in the</p> <p>11 area where the presence of NDMA was suspected</p> <p>12 to elute."</p> <p>13 Does that refresh your memory</p> <p>14 that the FDA also disagreed with ZHP's</p> <p>15 explanation regarding the difficulty in</p> <p>16 detecting NDMA?</p> <p>17 MR. BERNARDO: Object to the</p> <p>18 form of the question.</p> <p>19 THE WITNESS: I disagree with</p> <p>20 this paragraph. My disagreement was</p> <p>21 also reflected in our response to what</p> <p>22 was written by FDA in this paragraph.</p> <p>23 That was because,</p> <p>24 retrospectively, nobody at that time</p>
<p style="text-align: right;">Page 35</p> <p>1 form of the question.</p> <p>2 THE WITNESS: Now I see this</p> <p>3 paragraph.</p> <p>4 Indeed, FDA wrote this</p> <p>5 paragraph regarding the response we</p> <p>6 filed for the inspection.</p> <p>7 And with regards to the</p> <p>8 evaluation of the investigation, FDA</p> <p>9 did write -- did write such a</p> <p>10 paragraph when we tried to respond to</p> <p>11 the finding of that deviation, the</p> <p>12 second one.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Let's go to page 2.</p> <p>15 In the second-to-last</p> <p>16 paragraph, the FDA stated to ZHP, "Your</p> <p>17 response states that NDMA was difficult to</p> <p>18 detect. However, if you had investigated</p> <p>19 further, you may have found indicators in</p> <p>20 your residual solvent chromatograms alerting</p> <p>21 you to the presence of NDMA. For example,</p> <p>22 you told our investigators you were aware of</p> <p>23 a peak that eluted after the toluene peak in</p> <p>24 valsartan API residual solvent chromatograms</p>	<p style="text-align: right;">Page 37</p> <p>1 was aware of the existence of NDMA in</p> <p>2 valsartan. Now, of course, everything</p> <p>3 is very clear. But, retrospectively,</p> <p>4 had we known the existence of the</p> <p>5 NDMA, we would have found that was</p> <p>6 also in our response to FDA.</p> <p>7 I also listed FDA's statement</p> <p>8 in the list of documents, and I also</p> <p>9 believed that typically if we are</p> <p>10 aware of one impurity, we would</p> <p>11 develop the analytical method</p> <p>12 accompanying.</p> <p>13 At that time with regard to</p> <p>14 NDMA, nobody was aware of that, so we</p> <p>15 developed the analytical method</p> <p>16 according to the common industry</p> <p>17 practice as well as the FDA's</p> <p>18 requirement.</p> <p>19 But at that time nobody knew</p> <p>20 what NDMA was. So, as I said, had we</p> <p>21 known the method, the impurity, we</p> <p>22 would have developed the method</p> <p>23 accordingly. Since we didn't have the</p> <p>24 method, we were not aware of such an</p>

<p style="text-align: right;">Page 38</p> <p>1 impurity in the existence.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Looking now at the last full</p> <p>4 paragraph on page 2 of the warning letter,</p> <p>5 the FDA states, "Your response also states</p> <p>6 that you were not the only firm to identify</p> <p>7 NDMA in valsartan API. In your case, FDA</p> <p>8 analyses of samples identified amounts of</p> <p>9 NDMA in valsartan API manufactured at your</p> <p>10 firm that were significantly higher than the</p> <p>11 NDMA levels in valsartan API manufactured by</p> <p>12 other firms. FDA has grave concerns about</p> <p>13 the potential presence of mutagenic</p> <p>14 impurities in all intermediates and API</p> <p>15 manufactured at your facility, both because</p> <p>16 of the data indicating the presence of</p> <p>17 impurities in API manufactured by multiple</p> <p>18 processes, and because of the significant</p> <p>19 inadequacies in your investigation."</p> <p>20 Does that refresh your memory</p> <p>21 that the FDA also disagreed with ZHP's</p> <p>22 explanations? Does that help you to remember</p> <p>23 that?</p> <p>24 MR. BERNARDO: Object to the</p>	<p style="text-align: right;">Page 40</p> <p>1 announcement made by FDA and was made</p> <p>2 aware of that. Such a position was</p> <p>3 also reflected in our response to FDA.</p> <p>4 We were very clear about the whole</p> <p>5 process.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. The findings by the FDA</p> <p>8 constituted violations of cGMP and thus met</p> <p>9 the definition of "adulteration" as you</p> <p>10 understand the definition of "adulteration,"</p> <p>11 correct?</p> <p>12 MR. BERNARDO: Object to the</p> <p>13 form of the question.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. I'll ask it differently. Let</p> <p>16 me withdraw the question and start over.</p> <p>17 The deviations found by the FDA</p> <p>18 met the definition for "adulteration,"</p> <p>19 correct?</p> <p>20 MR. BERNARDO: Object to the</p> <p>21 form of the question.</p> <p>22 THE WITNESS: I don't quite get</p> <p>23 your question. I am sorry, I don't</p> <p>24 know what you're asking about.</p>
<p style="text-align: right;">Page 39</p> <p>1 form of the question.</p> <p>2 THE WITNESS: I found</p> <p>3 discrepancy between the translation</p> <p>4 given by the interpreter just now and</p> <p>5 the Chinese version of the warning</p> <p>6 letter. I don't know what caused the</p> <p>7 discrepancy in translation.</p> <p>8 However, based on the Chinese</p> <p>9 translation provided by my colleagues</p> <p>10 for this FDA warning letter, after</p> <p>11 their investigation, FDA did provide</p> <p>12 such a view based on their awareness</p> <p>13 of NDMA; therefore, their conclusion</p> <p>14 was a respective conclusion, because</p> <p>15 at that time everyone would know the</p> <p>16 existence of NDMA.</p> <p>17 That was the base where FDA</p> <p>18 thought our investigation was not</p> <p>19 sufficient. However, back at that</p> <p>20 time nobody was aware of NDMA.</p> <p>21 In our response to FDA, we</p> <p>22 stated that ZHP was not the only firm</p> <p>23 that identified NDMA. That was</p> <p>24 because we reviewed the public</p>	<p style="text-align: right;">Page 41</p> <p>1 BY MR. SLATER:</p> <p>2 Q. The deviations discussed by the</p> <p>3 FDA in their warning letter constituted</p> <p>4 adulteration of the valsartan, correct?</p> <p>5 MR. BERNARDO: Object to the</p> <p>6 form of the question.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Let me ask the question again.</p> <p>9 Let me withdraw it and ask it again.</p> <p>10 Based on the deviations from</p> <p>11 cGMP found by the FDA, the valsartan was</p> <p>12 adulterated, correct?</p> <p>13 MR. BERNARDO: Object to the</p> <p>14 form of the question.</p> <p>15 THE WITNESS: Maybe I already</p> <p>16 spoke in my prior statement, the term</p> <p>17 "adultration" -- "adulteration,"</p> <p>18 rather, is a term that FDA would use.</p> <p>19 That's okay. That's within the scope</p> <p>20 of their authority.</p> <p>21 Due to what they thought was a</p> <p>22 deviation from the cGMP, FDA issued in</p> <p>23 their warning letter in November 2018</p> <p>24 that that was adulteration. However,</p>

<p style="text-align: right;">Page 42</p> <p>1 that doesn't mean that valsartan 2 itself was adulterated. 3 MR. BERNARDO: Adam, I've been 4 trying to let you finish this line, 5 but we've been going for almost an 6 hour and a half, if there's a good 7 time to take a break. 8 MR. SLATER: I'd like to go 9 another five minutes or so and just 10 try to finish this question off. 11 MR. BERNARDO: Sure. I've been 12 trying not to interrupt, but we've 13 been going an hour and a half, and I 14 just want to make sure -- 15 MR. SLATER: I'm fine going as 16 long. I mean, if the witness doesn't 17 need a break and I don't need a break, 18 I don't know that we need to stop. 19 But let me go for a couple more 20 minutes, and if you want to have a 21 break, I can't stop you. That's why I 22 load up the food on my desk. 23 MR. BERNARDO: I need the 24 opposite of that.</p>	<p style="text-align: right;">Page 44</p> <p>1 A. I don't get the translation. 2 Could the interpreter repeat the rendition? 3 I wonder what time frame are 4 you referring to, or what specific time point 5 are you referring to? 6 In terms of the time frame in 7 my response to you, actually, when we found 8 out the existence of NDMA in valsartan in 9 June 2018, we terminated the manufacturing. 10 Prior to that time, we did manufacture 11 valsartan using zinc chloride process. 12 MR. SLATER: If you want to 13 take a break, we can take a break now. 14 MR. BERNARDO: Thank you, Adam. 15 Appreciate it. 16 THE VIDEOGRAPHER: The time 17 right now is 8:35 a.m. We're off the 18 record. 19 (Whereupon, a recess was 20 taken.) 21 THE VIDEOGRAPHER: The time 22 right now is 8:49 a.m. We're back on 23 the record. 24 ///</p>
<p style="text-align: right;">Page 43</p> <p>1 BY MR. SLATER: 2 Q. Based on your understanding of 3 the definition of "adulteration," because of 4 the deviations from cGMP found by the FDA, 5 the valsartan manufactured with the zinc 6 chloride process was adulterated, correct? 7 MR. BERNARDO: Object to the 8 form of the question. 9 THE WITNESS: That is not 10 correct. I totally disagree. It was 11 in November 2018 that FDA issued this 12 warning letter. 13 However, before November 2018, 14 ZHP already terminated the 15 manufacturing of valsartan using zinc 16 chloride process in June of 2018. 17 Therefore, I do not agree with 18 the statement that the products made 19 by ZHP was adulterated, according to 20 FDA's warning letter. 21 BY MR. SLATER: 22 Q. You understand the FDA was 23 talking about the valsartan API manufactured 24 with the zinc chloride process, correct?</p>	<p style="text-align: right;">Page 45</p> <p>1 BY MR. SLATER: 2 Q. During your preparation for 3 this deposition, did you become aware of the 4 existence of David Chesney? 5 A. No. 6 Q. Are you aware that there's a 7 person named David Chesney that was hired to 8 be the cGMP expert witness on behalf of ZHP 9 in this litigation? 10 A. I'm not aware of that. 11 Q. Were you aware that 12 Mr. Chesney, when he had his deposition 13 taken, testified that ZHP violated cGMP in 14 its risk assessment in connection with the 15 manufacturing process for the zinc chloride 16 manufacturing process? 17 MR. BERNARDO: Object to the 18 form of the question. 19 BY MR. SLATER: 20 Q. Let me reask the question. I 21 think I double-spoke at the end, so I think 22 it needs to be asked again. 23 During your preparation for 24 this deposition, did you become aware that</p>

<p style="text-align: right;">Page 46</p> <p>1 David Chesney, ZHP's cGMP expert, testified 2 that ZHP violated cGMP in connection with the 3 manufacture and manufacturing process for the 4 valsartan manufactured with the zinc chloride 5 process? 6 MR. BERNARDO: Object to the 7 form of the question. 8 THE WITNESS: I'm not aware of 9 that. 10 BY MR. SLATER: 11 Q. You were given certain expert 12 reports as part of your preparation for this 13 deposition. Wouldn't you have liked to have 14 seen the expert deposition of the cGMP expert 15 for ZHP? 16 MR. BERNARDO: Object to the 17 form of the question. 18 THE WITNESS: I did review some 19 of the expert reports, especially the 20 health risks. As I told you before, I 21 read the report by Dr. Chodosh and I 22 communicated with him. 23 So my first point is on the 24 topic of adulteration, that is related</p>	<p style="text-align: right;">Page 48</p> <p>1 position in our response is that we 2 never violated any cGMP requirements. 3 We were always in compliance with 4 cGMP. 5 BY MR. SLATER: 6 Q. Earlier you said that ZHP did a 7 lot of work to improve its processes. The 8 reason that ZHP had to improve its processes 9 is because they violated cGMP, right? 10 MR. BERNARDO: Object to the 11 form of the question. 12 THE WITNESS: In response to 13 your question, our company has been in 14 compliance with cGMP from beginning to 15 end. 16 In order to work with FDA, in 17 our response to FDA we made it very 18 clear that we have been in compliance 19 with cGMP. 20 However, in order to work with 21 them, we did a lot of work in a 22 proactive and responsible way to make 23 some improvements and enhancements. 24 It has always been our</p>
<p style="text-align: right;">Page 47</p> <p>1 to GMP. As the person in charge of 2 QA, I engage in GMP activities, so I 3 don't know what you mean. 4 As for FDA's warning letter, 5 requests, or questions, we always try 6 to respond seriously by organizing 7 human resources for such responses. 8 So I don't know what you mean. 9 BY MR. SLATER: 10 Q. You were given the reports of 11 certain defense experts. Would you have 12 liked to have seen Mr. Chesney's deposition, 13 since he was ZHP's expert on GMP and 14 testified that ZHP violated cGMP in the zinc 15 chloride manufacturing process? 16 MR. BERNARDO: Object to the 17 form of the question. 18 THE WITNESS: When I was trying 19 to get familiar with the topics, I was 20 not made aware of that. That is why I 21 did not have any communication with 22 him or had the chance to review his 23 report. That's number one. 24 Number two, our company's</p>	<p style="text-align: right;">Page 49</p> <p>1 company's position that we've been in 2 compliance with cGMP. The reason we 3 did a lot of work for improvement and 4 enhancement was to work with FDA, not 5 because we violated cGMP. 6 So we have always been very 7 clear in our response to reflect the 8 company's position. That is also 9 eventually recognized by FDA in their 10 approval. 11 BY MR. SLATER: 12 Q. You said that your company was 13 always proactive and responsible in the steps 14 it took, but let's look at page 4 of the 15 warning letter again and address what the FDA 16 had to say about that. 17 Let's look at the 18 second-to-last paragraph. The second-to-last 19 paragraph says, "Your response does not 20 describe sufficient corrective actions to 21 ensure that your firm has adequate change 22 management procedures in place: (1) to 23 thoroughly evaluate your API manufacturing 24 process, including changes to those</p>

<p style="text-align: right;">Page 50</p> <p>1 processes; and (2) to detect any unsafe 2 impurities, including potentially mutagenic 3 impurities. For FDA's current thinking on 4 control of potentially mutagenic impurities, 5 see FDA's guidance document M7(R1) Assessment 6 and Control of DNA Reactive (Mutagenic) 7 Impurities in Pharmaceuticals To Limit 8 Potential Carcinogenic Risk for approaches 9 that FDA considers appropriate for evaluating 10 mutagenic impurities, at," and then there's a 11 link there. 12 So, in fact, does that refresh 13 your memory that the FDA was not satisfied 14 with ZHP's proposed corrective actions and 15 forced ZHP to do more? 16 MR. BERNARDO: Object to the 17 form of the question. 18 THE WITNESS: Indeed, in this 19 warning letter FDA made such writings 20 in response to our prior response and 21 made such requests. Indeed, it was 22 written here. However, it doesn't 23 mean that we violated GMP. I do not 24 agree with such interpretation.</p>	<p style="text-align: right;">Page 52</p> <p>1 BY MR. SLATER: 2 Q. Looking at the first full 3 sentence om -- rephrase. 4 Looking at the first full 5 paragraph, which is only a sentence, on 6 page 6 of the FDA warning letter, the FDA 7 informs ZHP, "FDA placed your firm on Import 8 Alert 66-40 on September 28, 2018." 9 And you understand that ZHP was 10 placed on Import Alert because of the cGMP 11 violations found in connection with the zinc 12 chloride manufacturing process, right? 13 MR. BERNARDO: Object to the 14 form of the question. 15 THE WITNESS: Judging from the 16 content of this letter, I do not see 17 any causal effect relationship between 18 the two. I'm aware that FDA did put 19 us on such an Import Alert. 20 MR. SLATER: Hello? Can you 21 guys hear me? 22 MR. BERNARDO: Yes. You did 23 seem to freeze for a minute, but... 24 MR. SLATER: So where are we?</p>
<p style="text-align: right;">Page 51</p> <p>1 FDA, over here, indeed wrote 2 down what they thought would be a 3 better corrective action as a 4 regulatory authority. 5 (Zoom technical issue.) 6 MR. SLATER: I'm back. I guess 7 I disappeared for a second, and I 8 think I lost -- 9 MR. BERNARDO: You disappeared 10 again, in an interesting pose. 11 THE VIDEOGRAPHER: Should I go 12 off the record? 13 MR. BERNARDO: Sure. 14 THE VIDEOGRAPHER: The time 15 right now is 9:06 a.m. We're off the 16 record. 17 (Off the record for technical 18 issue.) 19 THE VIDEOGRAPHER: The time 20 right now is 9:09 a.m. We're back on 21 the record. 22 MR. SLATER: Okay. Let's go to 23 page 6, Chris. Great. 24 ///</p>	<p style="text-align: right;">Page 53</p> <p>1 I think you were reading the question 2 to the witness, Dr. Shao? 3 MR. BERNARDO: No, I thought 4 she answered and you had her answer. 5 MR. SLATER: You know what, I 6 didn't hear the answer. Can I have 7 the answer read to me, please? I must 8 have missed it when I was stage left 9 again. 10 (Whereupon, the reporter read 11 back the answer: 12 "ANSWER: Judging from the 13 content of this letter, I do not see 14 any causal effect relationship between 15 the two. I'm aware that FDA did put 16 us on such an Import Alert.") 17 BY MR. SLATER: 18 Q. The next paragraph says -- 19 rephrase. 20 The next paragraph of the 21 warning letter states, "Until you correct all 22 deviations completely and we confirm your 23 compliance with CGMP, FDA may withhold 24 approval of any new applications or</p>

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1 supplements listing your firm as a drug
2 manufacturer."
3 So you understood that FDA was
4 taking this action because of the deviations
5 from cGMP, correct?
6 MR. BERNARDO: Object to the
7 form of the question.
8 THE WITNESS: That
9 interpretation is incorrect. I
10 disagree with such a view.
11 In FDA's warning letter, they
12 did state such procedure that until
13 the corrections were completely made,
14 all the applications submitted by our
15 company, as well as the supplements,
16 will be upheld. That's their
17 procedure.
18 We're aware of that, but that
19 doesn't mean that we violated the
20 cGMP.
21 BY MR. SLATER:
22 Q. The corrections that the FDA
23 was referring to were corrections of the cGMP
24 violations listed in this letter, correct?

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1 MR. BERNARDO: Object to the
2 form of the question.
3 INTERPRETER SHAO: The
4 interpreter was asked to repeat the
5 rendition.
6 THE WITNESS: The corrections
7 that FDA was referring to were the
8 corrections for the deviations from
9 the cGMP listed in this warning
10 letter, as we discussed before.
11 BY MR. SLATER:
12 Q. And, therefore, you agree that
13 ZHP had violated cGMP and needed to correct
14 those violations, correct?
15 MR. BERNARDO: Object to the
16 form of the question.
17 THE WITNESS: That is
18 incorrect. Why we took some actions
19 for improvement was to work with FDA.
20 That was very clear with FDA in our
21 response letter. That has always been
22 our position, that we did not violate
23 any cGMP.
24 ///

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1 BY MR. SLATER:
2 Q. Am I correct that no matter
3 what evidence the jury hears at the trial of
4 this case, your answer on behalf of ZHP will
5 be that ZHP did nothing in violation of cGMP
6 and acted appropriately in all things?
7 MR. BERNARDO: Object to the
8 form of the question.
9 THE WITNESS: I don't
10 understand what you're referring to by
11 evidence of violation of cGMP that the
12 jury would hear in the trial of this
13 case.
14 I did mention in my prior
15 statement that in our response to this
16 warning letter, we made it very clear
17 that it has always been the position
18 of our company that we're being in
19 compliance with cGMP.
20 That was so in our response
21 letter. That was also the same in our
22 communication with FDA afterwards. We
23 have always been making that very
24 clear.

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1 BY MR. SLATER:
2 Q. It will always be ZHP's
3 position that it did nothing wrong and never
4 violated cGMP in the manufacture of
5 valsartan, no matter what evidence is shown,
6 no matter what documents are seen, and no
7 matter what testimony is provided by
8 witnesses, correct?
9 MR. BERNARDO: Object to the
10 form of the question.
11 THE WITNESS: I disagree
12 with -- I disagree with your
13 statement. That is incorrect.
14 Our manufacturing of valsartan
15 in ZHP could trace as back as in 2011
16 or maybe 2010. During the whole
17 period of time, we have conducted a
18 series of work before we started to
19 manufacture valsartan in compliance
20 with GMP.
21 We met the requirement of FDA.
22 We did not start in the manufacturing
23 of valsartan until the regulatory
24 procedure and approval was complete.

<p style="text-align: right;">Page 58</p> <p>1 During the process, FDA 2 conducted many inspections and came up 3 with the conclusion that we were in 4 the -- in compliance with GMP, except 5 for this inspection. That was because 6 the inspection was made after the 7 discovery of NDMA. Therefore, they 8 issued this warning letter. 9 In this warning letter, they 10 listed those findings which our 11 company made a response. Based on the 12 above points, actually in addition to 13 that, we were audited many times by 14 EU, by Japanese, and Korean official 15 authorities, and their conclusion was 16 always that we were in compliance with 17 cGMP. 18 So it's not like no matter what 19 evidence was produced, that our 20 company's position would be the same, 21 that we were in compliance with cGMP. 22 That's why I disagree with your 23 statement. 24 ///</p>	<p style="text-align: right;">Page 60</p> <p>1 I was just wondering why you 2 would come up with such a conclusion. 3 You know, as discussed before, after 4 we made response to FDA, FDA 5 eventually gave the approval by 6 issuing this IEA report. Actually, 7 EIA report. 8 Actually, in 2012, we already 9 received this EIA report from FDA. 10 Do you mean that we have been 11 violating the cGMP all the time? What 12 do you mean by saying that? 13 BY MR. SLATER: 14 Q. It was never acceptable for 15 there to be NDMA in the valsartan that ZHP 16 was selling, correct? 17 A. I don't quite understand your 18 question. As I said in my prior statement, 19 the reason why we were selling valsartan in 20 the US and we were manufacturing valsartan 21 was because of the approval by the FDA. We 22 met their requirement. 23 Q. It's your testimony that the 24 FDA approved the sale of valsartan containing</p>
<p style="text-align: right;">Page 59</p> <p>1 BY MR. SLATER: 2 Q. As you just said, once the FDA 3 found out about the NDMA in the valsartan, it 4 investigated, it found cGMP violations, it 5 issued a warning letter, and it put ZHP on 6 the Import Alert, correct? 7 MR. BERNARDO: Object to the 8 form of the question. 9 THE WITNESS: I don't see any 10 causal effect relationship between the 11 two. The warning letter issued by FDA 12 made it very clear the reason why they 13 issued such a letter was because they 14 believed that we failed to meet their 15 requirement by two deviations, and 16 that is not because we violated cGMP 17 simply by manufacturing valsartan. 18 We have already discussed about 19 that, and I've already stated in my 20 prior statement that when we were 21 manufacturing valsartan in June 2018, 22 we found NDMA and we reported that 23 discovery to FDA. Afterwards, FDA 24 organized this inspection.</p>	<p style="text-align: right;">Page 61</p> <p>1 NDMA? 2 A. That is not my testimony. I 3 think you misunderstood me. 4 Before June 2018, we didn't 5 know about NDMA, and I believe FDA was not 6 aware of NDMA. That's why we were given the 7 approval to manufacture valsartan. 8 However, in June 2018, after we 9 discovered NDMA, we conducted investigations, 10 suspended manufacturing, and took 11 corresponding actions. 12 Q. The FDA would never have 13 approved the sale of ZHP's valsartan if it 14 knew that there was NDMA in it. 15 You agree with that, right? 16 MR. BERNARDO: Object to the 17 form of the question. 18 THE WITNESS: First, I don't 19 think your hypothesis is legitimate. 20 That is because when we were applying 21 for approval for manufacturing ND- -- 22 manufacturing valsartan, we were not 23 aware of NDMA. Neither were they. 24 Even if your hypothesis were</p>

<p style="text-align: right;">Page 62</p> <p>1 legitimate, FDA would have asked our 2 company to take actions in quality 3 control to limit the content of NDMA 4 had they been aware of the existence 5 of NDMA, and would have asked us to 6 take corresponding actions. 7 In other words, I believe our 8 company would have done our best to 9 meet the requirement of FDA. 10 BY MR. SLATER: 11 Q. One of the requirements the FDA 12 expected ZHP to meet would have been 13 compliance with ICH M7 at all times that ZHP 14 sold the valsartan, correct? 15 A. I'm not sure of the scope of 16 sale that you're referring to. 17 Q. At all times, the FDA expected 18 ZHP to comply with ICH M7 in its assessment 19 and control of DNA-reactive mutagenic 20 impurities, correct? 21 MR. BERNARDO: Object to the 22 form of the question. 23 THE WITNESS: I don't quite 24 understand your question, but I'll</p>	<p style="text-align: right;">Page 64</p> <p>1 aware of NDMA until June 2018, nor was 2 FDA. Therefore, for something you 3 don't know, you really cannot do 4 anything about it. 5 Prior to that, because of the 6 unawareness of NDMA, you cannot accuse 7 us of violating ICH M7. Actually, our 8 company has always been in compliance 9 with ICH M7. 10 Therefore, I do not agree with 11 your statement that our company was 12 selling NDMA containing valsartan 13 knowingly, or on purpose, or 14 deliberately. 15 I would like to also add 16 something else. My first point is 17 that we were expected to be in 18 compliance with ICH M7 when we were 19 going through the regulatory process. 20 Otherwise, FDA would not have approved 21 our application. 22 It was FDA's observation that 23 we were in compliance with ICH M7, and 24 they also confirmed so through</p>
<p style="text-align: right;">Page 63</p> <p>1 give it a try. 2 First point I would like to 3 make is that ZHP as a drug 4 manufacturer has been expected by FDA 5 to meet the requirement of M7. 6 My second point is, our company 7 has always been in compliance with M7. 8 BY MR. SLATER: 9 Q. So you think that ZHP was in 10 compliance with ICH M7 when it was selling 11 valsartan that contained the 12 mutagenic/genotoxic impurity NDMA in the 13 United States? 14 MR. BERNARDO: Object to the 15 form of the question. 16 THE WITNESS: I don't agree 17 with your statement because I think 18 the causal effect relationship should 19 be the opposite; therefore, I believe 20 that your statement is completely 21 incorrect. 22 Our company has always been in 23 compliance with ICH M7 in controlling 24 impurities. However, we were not</p>	<p style="text-align: right;">Page 65</p> <p>1 multiple inspections. Otherwise, they 2 wouldn't have brought it up in their 3 previous inspections. 4 My second point is, had we 5 known the existence of NDMA prior to 6 2018, why did we delay the recall and 7 other work until then? What was the 8 reason we would do that? 9 BY MR. SLATER: 10 Q. There would never be an 11 acceptable reason to do that, right? 12 A. To do what? Are you referring 13 to the sales of valsartan? 14 Q. I'll ask the question 15 differently. 16 You just said if you had known 17 of the presence of NDMA, why did you delay 18 the recall until 2018. 19 My question to you is, you 20 agree that it never would have been 21 acceptable under any circumstances to delay 22 disclosure to the FDA and to your customers 23 once you found out that there was NDMA in the 24 valsartan, correct?</p>

<p style="text-align: right;">Page 66</p> <p>1 A. With regard to your 2 hypothetical question, I have to say that 3 indeed in June 2018, once we found out about 4 the existence of NDMA, we disclosed to FDA 5 right away, and we did our best to develop 6 analytical methods. 7 Q. Can you answer my question, 8 please? 9 A. I think I already gave you a 10 direct answer. 11 Had we known the existence of 12 NDMA prior to June 2018, we would have done 13 the same as we did in June 2018, which was 14 that we made an immediate disclosure to the 15 FDA, and we immediately started communication 16 with FDA and did our best to develop 17 analytical methods. 18 Q. You were required to take the 19 steps that you took in 2018 as soon as you 20 knew that there was NDMA in the valsartan, 21 correct? 22 A. We took also many actions at 23 that time, such as suspension of the 24 manufacturing and suspension of the sales and</p>	<p style="text-align: right;">Page 68</p> <p>1 learned that there was NDMA in the valsartan 2 at an earlier time, correct? 3 A. That is correct. 4 Q. In fact, as of at least 5 July 27, 2017, you and others in your company 6 knew that when valsartan was quenched with 7 sodium nitrite, it was forming NDMA, correct? 8 A. That is incorrect. 9 MR. BERNARDO: Adam, we've been 10 going over an hour. If you're going 11 to turn to that topic and we could 12 take a break, that would be good. 13 MR. SLATER: Sure. Sure. 14 MR. BERNARDO: Thank you. 15 MR. SLATER: Go off the record. 16 THE VIDEOGRAPHER: The time 17 right now is 9:52 a.m. We're off the 18 record. 19 (Whereupon, a recess was 20 taken.) 21 THE VIDEOGRAPHER: The time 22 right now is 10:08 a.m. We're back on 23 the record. 24 ///</p>
<p style="text-align: right;">Page 67</p> <p>1 locking up all the manufactured goods in the 2 warehouse. Those actions were taken 3 spontaneously. Nobody required us to do so. 4 Q. ZHP needed to take those steps 5 as soon as ZHP became aware that there was 6 NDMA in its valsartan, correct? 7 A. That was the decision we made 8 after the company conducted the deviation 9 investigation. 10 Q. My question that I'm asking you 11 to answer with a simple yes or no, please, as 12 soon as ZHP knew that there was NDMA in its 13 valsartan, it was required to disclose this 14 to the FDA and to its customers and to stop 15 selling the valsartan with the NDMA in it, 16 correct? 17 MR. BERNARDO: Object to the 18 form of the question. 19 BY MR. SLATER: 20 Q. Let me rephrase the question. 21 Let me withdraw it and ask it differently. 22 The steps that ZHP took in 23 June 2018, you would agree with me ZHP would 24 have needed to take the same steps if it had</p>	<p style="text-align: right;">Page 69</p> <p>1 BY MR. SLATER: 2 Q. A few moments ago you asked the 3 question why would ZHP not have disclosed the 4 presence of the NDMA in its valsartan as soon 5 as it knew. 6 And I guess in response to you 7 asking that question, I would pose the 8 possibility that ZHP was making so much 9 money, and in the words of Jun Du to the FDA 10 investigator, "dominating the world market 11 for valsartan," that that was the incentive 12 that unfortunately ZHP was swayed by and 13 didn't take action to stop selling the 14 NDMA-contaminated valsartan earlier. 15 That's certainly something that 16 could have happened here, right? 17 A. This is incorrect. This is 18 completely incorrect. I'm not aware of the 19 statement made by Jun Du. However, I don't 20 believe your statement is correct. 21 Q. If ZHP failed to disclose the 22 presence of the NDMA earlier because ZHP 23 wanted to continue to profit from that 24 valsartan, that would have been completely</p>

<p style="text-align: right;">Page 70</p> <p>1 improper, correct?</p> <p>2 A. I found your statement sounds</p> <p>3 incredible. ZHP is a manufacturer of</p> <p>4 valsartan.</p> <p>5 I don't quite understand your</p> <p>6 statement, actually. Could Dr. Shao repeat a</p> <p>7 rendition?</p> <p>8 Well, if the company wants to</p> <p>9 make more profits, then it could have taken</p> <p>10 better approaches, such as removal of the</p> <p>11 impurities. By doing that, the company could</p> <p>12 have made more profits.</p> <p>13 Q. ZHP only disclosed the presence</p> <p>14 of the NDMA in the valsartan after Novartis</p> <p>15 forced ZHP to do so, right?</p> <p>16 A. That is incorrect.</p> <p>17 Q. Have you read the e-mails</p> <p>18 between ZHP and Novartis that led to the</p> <p>19 disclosure of the NDMA in the valsartan?</p> <p>20 A. While I was organizing the</p> <p>21 deviation investigation, I already read that</p> <p>22 e-mail.</p> <p>23 In that e-mail, Novartis was</p> <p>24 only stating that they were suspecting that</p>	<p style="text-align: right;">Page 72</p> <p>1 All I know is that he works in</p> <p>2 CEMAT, and he is someone that would conduct</p> <p>3 analysis on impurities.</p> <p>4 Q. He was in charge of the lab for</p> <p>5 process and degradation impurity research at</p> <p>6 CEMAT, correct?</p> <p>7 A. He was not the person in</p> <p>8 charge. I believe Min Li is actually the</p> <p>9 person in charge.</p> <p>10 Q. Min Li was in charge of all of</p> <p>11 CEMAT. Jinsheng Lin was in charge of the lab</p> <p>12 for process and degradation impurity</p> <p>13 research, correct?</p> <p>14 A. Are you referring to now or</p> <p>15 back in 2017?</p> <p>16 Q. 2017.</p> <p>17 A. If you're referring to the time</p> <p>18 in 2017, if my memory serves me right, he was</p> <p>19 just a regular analytical personnel at CEMAT.</p> <p>20 Because recently I noticed there was some</p> <p>21 promotions, if my memory serves me right.</p> <p>22 MR. SLATER: Chris, let's put</p> <p>23 up Exhibit 431, please.</p> <p>24 ///</p>
<p style="text-align: right;">Page 71</p> <p>1 the impurity might be NDMA.</p> <p>2 Q. And then ZHP confirmed it was</p> <p>3 NDMA, and ZHP was not moving quickly enough,</p> <p>4 and Novartis had to threaten ZHP to force ZHP</p> <p>5 to disclose the NDMA, correct?</p> <p>6 A. I don't know where you came up</p> <p>7 with that narrative. That's not what I'm</p> <p>8 aware of.</p> <p>9 Q. Let's go back to the July 27,</p> <p>10 2017 e-mail that Jinsheng Lin sent to you and</p> <p>11 copied several people.</p> <p>12 You have that e-mail in your</p> <p>13 binder, right?</p> <p>14 A. That is correct.</p> <p>15 Q. It's item number 11 in your</p> <p>16 binder, correct?</p> <p>17 A. Let me check. That is correct.</p> <p>18 Item number 11 is that e-mail, while item</p> <p>19 number 12 is the attachment to that e-mail.</p> <p>20 Q. Jinsheng Lin is a Ph.D.</p> <p>21 organic chemist, correct?</p> <p>22 A. Since we worked in different</p> <p>23 departments, I was never familiar with his</p> <p>24 qualifications, so I don't know about that.</p>	<p style="text-align: right;">Page 73</p> <p>1 (Whereupon, Exhibit Number</p> <p>2 ZHP-431 was previously marked for</p> <p>3 identification.)</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Actually, you know what, you</p> <p>6 can actually give -- Exhibit 431 is the</p> <p>7 version in Chinese and Exhibit 432 is the</p> <p>8 English translation of the PowerPoint. Let's</p> <p>9 work with 432 on the screen, but you can</p> <p>10 certainly -- I'd like to give the witness 431</p> <p>11 so she can see that as well.</p> <p>12 (Whereupon, Exhibit Number</p> <p>13 ZHP-432 was previously marked for</p> <p>14 identification.)</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Let's go to the third page.</p> <p>17 This is a PowerPoint that we've</p> <p>18 been provided that my understanding is dated</p> <p>19 November 2017 regarding CEMAT.</p> <p>20 Do you see that?</p> <p>21 A. I don't know. I've never seen</p> <p>22 this document before.</p> <p>23 Q. So in your work that you did to</p> <p>24 prepare for this deposition, you didn't see</p>

<p style="text-align: right;">Page 74</p> <p>1 this PowerPoint, which has been used in other 2 depositions, in order to give you background 3 about Jinsheng Lin's role at the company in 4 2017, correct?</p> <p>5 MR. BERNARDO: Object to the 6 form of the question.</p> <p>7 THE WITNESS: That's not 8 correct. As I said before, in order 9 to prepare for this deposition, I 10 worked very hard to get familiar with 11 the topics with regard to the three 12 topics that I have to speak on. I did 13 a lot of work in preparation.</p> <p>14 But this document was certainly 15 not on the list of the documents that 16 I needed to review. Had you told me 17 that I had to review this document, I 18 would have reviewed this document.</p> <p>19 Anyway, with that, I have to 20 say even though I already reviewed a 21 lot of documents, that doesn't mean 22 that I reviewed all the documents.</p> <p>23 BY MR. SLATER: 24 Q. Looking now at the third page</p>	<p style="text-align: right;">Page 76</p> <p>1 Chris. You can show her the cover.</p> <p>2 THE WITNESS: Can you scroll 3 down to second page?</p> <p>4 Now I see. It was Wen Quan Zhu 5 that prepared this document. Wen Quan 6 Zhu's named is spelled W-E-N, Q-U-A-N, 7 last name Z-H-U. But the document 8 didn't say when it was prepared.</p> <p>9 BY MR. SLATER: 10 Q. I'm representing to you that 11 the information we have says November 2017.</p> <p>12 A. Is that so?</p> <p>13 Oh, now I know that since CEMAT 14 is located at the corporate headquarters in 15 the Xunqiao site of Linhai County, Xunqiao 16 spelled as X-U-N-Q-I-A-O, while I work at the 17 Chuannan site, also in Linhai County, in the 18 Chemical Engineering Industrial Park. So 19 we're looking at different sites and 20 different departments.</p> <p>21 I was never familiar with the 22 title and job description of Jinsheng Lin, 23 and I didn't make any effort to gather 24 information regarding that during my</p>
<p style="text-align: right;">Page 75</p> <p>1 of this PowerPoint, you can see that it is 2 titled that it's -- rephrase.</p> <p>3 Looking now at the third page 4 of this PowerPoint, it refers to the lab or 5 laboratory for process and degradation 6 impurity research and says that the 7 responsible person for that laboratory was 8 Jinsheng Lin, correct?</p> <p>9 MR. BERNARDO: Objection to the 10 form of the question.</p> <p>11 THE WITNESS: As I mentioned 12 earlier, my English is poor. If 13 possible, could someone translate this 14 page for me since I do not understand 15 what it says in English here?</p> <p>16 MR. SLATER: The version in 17 Chinese or Mandarin is Exhibit 431.</p> <p>18 Chris, if you could put that 19 up.</p> <p>20 THE WITNESS: Can you show me 21 the cover of this document so that I 22 can figure out who prepared this 23 document?</p> <p>24 MR. SLATER: You can do that,</p>	<p style="text-align: right;">Page 77</p> <p>1 preparation.</p> <p>2 In the past, I did not get to 3 interact with CEMAT. Only once there was an 4 issue and we needed their support to resolve 5 the issues, we would approach.</p> <p>6 MR. SLATER: Let's go back to 7 the third page.</p> <p>8 BY MR. SLATER: 9 Q. This page -- rephrase.</p> <p>10 The third page of this 11 PowerPoint shows that Jinsheng Lin was the 12 responsible person in this laboratory for 13 process and degradation impurity research, 14 correct? That's what it says on the page, 15 correct?</p> <p>16 MR. BERNARDO: Object to the 17 form of the question.</p> <p>18 THE WITNESS: That's what it 19 says on this page.</p> <p>20 BY MR. SLATER: 21 Q. Looking now at the e-mail of 22 July 27, 2017, that Jinsheng Lin addressed to 23 you. Do you see that in front of you?</p> <p>24 MR. SLATER: You can take this</p>

<p style="text-align: right;">Page 78</p> <p>1 document down, Chris.</p> <p>2 THE WITNESS: I see it.</p> <p>3 MR. SLATER: And we'll put up</p> <p>4 on the screen 296, which is the</p> <p>5 English version, but the witness can</p> <p>6 refer to the Exhibit 295, which is the</p> <p>7 original Mandarin.</p> <p>8 That's not the exhibit.</p> <p>9 (Whereupon, Exhibit Numbers</p> <p>10 ZHP-295 and ZHP-296 were previously</p> <p>11 marked for identification.)</p> <p>12 BY MR. SLATER:</p> <p>13 Q. This e-mail was written to you</p> <p>14 and copied to multiple people, correct?</p> <p>15 A. That is correct.</p> <p>16 Q. Let's look at the second page.</p> <p>17 At the top, one of the things</p> <p>18 that Jinsheng Lin wrote in this e-mail is</p> <p>19 that nitrosodimethylamine occurs in valsartan</p> <p>20 when it's quenched with sodium nitrite.</p> <p>21 And, in fact, you can confirm</p> <p>22 to me that's a true statement; that was the</p> <p>23 root cause for the NDMA in the zinc chloride</p> <p>24 process valsartan, correct?</p>	<p style="text-align: right;">Page 80</p> <p>1 under oath already, right?</p> <p>2 MR. BERNARDO: Object to the</p> <p>3 form of the question.</p> <p>4 THE WITNESS: I don't quite get</p> <p>5 your question. Indeed, I recall this</p> <p>6 e-mail was asked about in my prior</p> <p>7 deposition. However, you can resort</p> <p>8 to the relevant evidence for my</p> <p>9 response.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. It's a true statement that in</p> <p>12 July 2017 there was NDMA in the valsartan</p> <p>13 that your company was manufacturing, correct?</p> <p>14 MR. BERNARDO: Object to the</p> <p>15 form of the question.</p> <p>16 THE WITNESS: I don't know how</p> <p>17 to respond to this question.</p> <p>18 Well, let me put it in this</p> <p>19 way. I believe the right way to put</p> <p>20 it is that not until June 2018 did we</p> <p>21 become aware of the existence of NDMA</p> <p>22 in valsartan that we manufactured</p> <p>23 prior to that date.</p> <p>24 ///</p>
<p style="text-align: right;">Page 79</p> <p>1 MR. BERNARDO: Object to the</p> <p>2 form of the question.</p> <p>3 THE WITNESS: That is</p> <p>4 incorrect. Actually, your</p> <p>5 interpretation did not reflect the</p> <p>6 intent of this sentence.</p> <p>7 I have to admit that this</p> <p>8 e-mail is poorly written and</p> <p>9 ambiguous, to be the least. However,</p> <p>10 your interpretation is oversimplified.</p> <p>11 You could not just take this sentence</p> <p>12 out of the context and come up with</p> <p>13 this interpretation, which did not</p> <p>14 reflect the true intention of Dr. Lin,</p> <p>15 which was confirmed through my</p> <p>16 communication with him.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. You realize you've already</p> <p>19 testified under oath in your prior deposition</p> <p>20 that the e-mail says in part that there was</p> <p>21 nitrosodimethylamine in valsartan and that it</p> <p>22 occurred when the valsartan was quenched with</p> <p>23 sodium nitrite.</p> <p>24 You know you testified to that</p>	<p style="text-align: right;">Page 81</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Please answer my question with</p> <p>3 a yes or a no.</p> <p>4 In July of 2017, there was NDMA</p> <p>5 in the valsartan manufactured by ZHP with the</p> <p>6 zinc chloride process, correct?</p> <p>7 A. A point of clarification. A</p> <p>8 point of clarification. Are you asking</p> <p>9 whether we were already aware that there was</p> <p>10 NDMA in the valsartan we manufactured with</p> <p>11 the zinc chloride process in July 2017?</p> <p>12 Is that what your question is</p> <p>13 about?</p> <p>14 Q. No. My question is, there was</p> <p>15 NDMA in the valsartan manufactured by ZHP</p> <p>16 with the zinc chloride process in July 2017,</p> <p>17 correct?</p> <p>18 MR. BERNARDO: Object to the</p> <p>19 form of the question.</p> <p>20 THE WITNESS: I don't know</p> <p>21 whether it is because of the</p> <p>22 difference between English and</p> <p>23 Chinese, I am still puzzled by your</p> <p>24 question. I will do my best to</p>

<p style="text-align: right;">Page 82</p> <p>1 respond to your question. 2 Not until June 2018 did we 3 become aware that there was NDMA in 4 the valsartan that we manufactured in 5 2017 using the zinc chloride process. 6 Prior to June 2018, we were not 7 aware of the existence of NDMA that we 8 manufactured using the zinc chloride 9 process; the existence of the NDMA in 10 the valsartan that we manufactured 11 using the zinc chloride process, that 12 is. 13 BY MR. SLATER: 14 Q. I have tables -- rephrase. 15 I have tables of NDMA test 16 results from testing of batches going back to 17 the first validation batches that were 18 manufactured in 2011 and then in 2014 and 19 forward. Every single one of those batches 20 of valsartan manufactured with the zinc 21 chloride process contained NDMA, correct? 22 MR. BERNARDO: Object to the 23 form of the question. 24 THE WITNESS: That is correct.</p>	<p style="text-align: right;">Page 84</p> <p>1 and Jinsheng Lin and eventually figured out, 2 after reading this e-mail again and again, 3 that this e-mail was trying to make a 4 comparison with NDMA when it was talking 5 about the toxicology of this impurity from 6 being the technical improvement of 7 irbesartan. 8 Q. And in making the comparison to 9 the NDMA in valsartan, Dr. Lin also pointed 10 out that the NDMA was forming when it was -- 11 when the valsartan was quenched with sodium 12 nitrite during the manufacturing process, 13 correct? That's what the words on the page 14 say. 15 A. That's incorrect. In order to 16 correctly interpret this e-mail, you have not 17 only to read through this e-mail, but also 18 the attachment. 19 In order to truthfully 20 understand the meaning of this e-mail, I did 21 a large amount of work, including 22 communicating with Jinsheng Lin himself. 23 Until then I fully understood the intention 24 of this e-mail by reading the e-mail from top</p>
<p style="text-align: right;">Page 83</p> <p>1 However, that was the result of 2 retrospective testing of all those 3 batches after we learned about the 4 existence of NDMA in valsartan in 5 June 2018. 6 BY MR. SLATER: 7 Q. When Jinsheng Lin said in his 8 July 27, 2017 e-mail that there was NDMA that 9 occurs in valsartan when quenched with sodium 10 nitrite, that was an accurate statement, 11 correct? 12 A. That's incorrect. I don't 13 think your interpretation was a correct 14 reflection of the intention of the author. 15 Q. That's what the words on the 16 page say, correct? 17 A. That's incorrect. That -- as I 18 stated in my prior testimony, this e-mail was 19 poorly written and complicated, as you could 20 see here, even though that was the words that 21 said so on this page. But the whole e-mail 22 is about the impurity found in the technical 23 improvement for irbesartan. 24 I communicated with Peng Dong</p>	<p style="text-align: right;">Page 85</p> <p>1 to bottom. 2 Q. The statement that the NDMA 3 occurred in valsartan when it was quenched 4 with sodium nitrite, that's a true statement, 5 and that's actually the root cause for the 6 NDMA in valsartan, correct? 7 MR. BERNARDO: Object to the 8 form of the question. 9 THE WITNESS: That's incorrect. 10 That's incorrect. That's completely 11 incorrect. 12 As I mentioned before, 13 Dr. Jinsheng Lin at that time was only 14 someone that would conduct analysis of 15 impurities at CEMAT. 16 Through communication with him, 17 I learned at that time he had very 18 limited knowledge of the process of 19 manufacturing valsartan. That 20 limitation was only to the attached 21 patent, from which he would try to 22 come up with this comparison of 23 Impurity K, nitroso compound, and 24 NDMA.</p>

<p style="text-align: right;">Page 86</p> <p>1 According to him, NDMA was a 2 quite common impurity. That's why he 3 wanted to use NDMA to have a 4 comparison with the impurity he found 5 in the technical improvement of 6 irbesartan. 7 Through communication with 8 Jinsheng Lin, he actually was not 9 aware of the NDMA in valsartan at all 10 at that time. 11 BY MR. SLATER: 12 Q. Let's go further down in the 13 e-mail to the second-to-last paragraph. 14 He says, "This is a common 15 problem in the production and synthesis of 16 sartan APIs. It is recommended to improve 17 other quenching processes (such as NaClO) 18 along with the optimization of the valsartan 19 sodium azide quenching process." 20 And I want to focus on the last 21 part. Do you see where it says that he was 22 recommending "the optimization of the 23 valsartan sodium azide quenching process"? 24 A. I see that paragraph. I see</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. So it's your testimony that 2 Jinsheng Lin accidentally correctly guessed 3 that there was NDMA in valsartan in July of 4 2017? That's your explanation? 5 MR. BERNARDO: Object to the 6 form of the question. 7 THE WITNESS: I completely 8 disagree with you. 9 BY MR. SLATER: 10 Q. So it's your testimony that 11 when Jinsheng Lin said there was NDMA in 12 valsartan, he really meant to say there's an 13 unknown nitrosamine in valsartan? 14 Do I understand you correctly? 15 MR. BERNARDO: Object to the 16 form of the question. 17 THE WITNESS: I don't 18 understand your question. Can the 19 interpreter repeat the rendition? 20 I don't agree with you. It is 21 incorrect. As I said before, Jinsheng 22 Lin was at that time only someone who 23 would conduct analysis in CEMAT, as 24 shown in the PowerPoint file. He was</p>
<p style="text-align: right;">Page 87</p> <p>1 the paragraph you just referred to. 2 Q. Are you aware that in the 3 deviation investigation report DC-18003, 4 there's a section that refers to valsartan 5 zinc chloride process optimization, and that 6 optimization which Dr. Lin had recommended in 7 2017 is exactly what your company did to try 8 to remove the NDMA from the valsartan? 9 Are you aware of that? 10 MR. BERNARDO: Object to the 11 form of the question. 12 THE WITNESS: I believe you 13 completely misunderstood what's 14 written here, as well as what's 15 written in DC-18003. I believe you 16 have a complete misunderstanding 17 regarding the two documents. 18 BY MR. SLATER: 19 Q. You know that NDMA is different 20 from Impurity K as that term is used in the 21 patent, right? Right? 22 A. Indeed, those two impurities 23 are different. They are both nitroso 24 compounds.</p>	<p style="text-align: right;">Page 89</p> <p>1 actually doing the impurity analysis 2 or impurity degradation analysis and 3 the structure confirmation. 4 CEMAT is located at the company 5 headquarters in Xunqiao, while 6 valsartan at that time was 7 manufactured at the Chuannan site. 8 I already communicated with 9 Jinsheng Lin. At that time we were 10 working in different sites, so his 11 understanding regarding the impurity 12 in valsartan was only limited to 13 Impurity K mentioned in that happened. 14 He at that time was not aware 15 of the existence of NDMA in valsartan. 16 That was because of the limitation of 17 the analytical method. 18 A good analytical method is 19 capable of testing out the targeting 20 impurities. At that time, the 21 analytical method failed to detect 22 that impurity, so Jinsheng Lin or we 23 did not have any awareness of the NDMA 24 in valsartan at that time.</p>

<p style="text-align: right;">Page 90</p> <p>1 BY MR. SLATER:</p> <p>2 Q. So it's your testimony that</p> <p>3 Jinsheng Lin didn't know there was NDMA in</p> <p>4 valsartan, yet in his e-mail he said there</p> <p>5 was NDMA in valsartan.</p> <p>6 MR. BERNARDO: Object to the</p> <p>7 form of the question.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Do I understand what you're</p> <p>10 saying?</p> <p>11 A. That is why I was confused when</p> <p>12 I was reading his e-mail in the first place,</p> <p>13 the same confusion you are having right now.</p> <p>14 Needless to say, this e-mail</p> <p>15 was poorly written, and it was hard to</p> <p>16 understand.</p> <p>17 Even when it was written in</p> <p>18 Chinese, I could not get what is said until I</p> <p>19 communicated with the author himself and read</p> <p>20 through not only the body of the e-mail, but</p> <p>21 also the attachment. Not until then did I</p> <p>22 figure out what it was saying.</p> <p>23 So it is understandable that</p> <p>24 when it is translated into English, you're</p>	<p style="text-align: right;">Page 92</p> <p>1 valsartan.</p> <p>2 In addition, he was not a</p> <p>3 technician of valsartan. He was not in</p> <p>4 charge of this product. His understanding</p> <p>5 regarding valsartan was only limited to the</p> <p>6 Impurity K mentioned in the attached patent,</p> <p>7 not NDMA.</p> <p>8 So if you look into the context</p> <p>9 of this e-mail, you can tell that at that</p> <p>10 time he was trying to make a comparison</p> <p>11 between NDMA and Impurity K and the impurity</p> <p>12 found in the technical improvement of</p> <p>13 irbesartan, since they were all nitroso</p> <p>14 compounds, and he was merely trying to make a</p> <p>15 toxicology comparison.</p> <p>16 Q. And to be very clear, the words</p> <p>17 on the page not only say that there was NDMA</p> <p>18 in valsartan; they also say that the NDMA</p> <p>19 occurred in the valsartan when it was</p> <p>20 quenched with sodium nitrite.</p> <p>21 Those words were accurate and</p> <p>22 true at the time the e-mail was written,</p> <p>23 correct?</p> <p>24 A. That's incorrect.</p>
<p style="text-align: right;">Page 91</p> <p>1 having a hard time understanding the content.</p> <p>2 Even when it was written in Chinese, I had</p> <p>3 the same problem, too.</p> <p>4 Q. Well, you actually aren't</p> <p>5 having trouble reading the e-mail, because we</p> <p>6 agree it says that there is NDMA in</p> <p>7 valsartan. We've already agreed on that,</p> <p>8 right? That's what the e-mail says, the</p> <p>9 words on the page. You've already told me</p> <p>10 that, right?</p> <p>11 A. Even though that sentence in</p> <p>12 the e-mail says so, you would not get the</p> <p>13 correct understanding until you look into the</p> <p>14 context.</p> <p>15 I failed to get what the e-mail</p> <p>16 said in the beginning until I had</p> <p>17 communication with the author, Jinsheng Lin.</p> <p>18 He told me at the time he was -- of the</p> <p>19 existence of NDMA in valsartan.</p> <p>20 He also -- I also told you at</p> <p>21 that time that was because there was no</p> <p>22 capable analytical method that would test out</p> <p>23 such impurity; therefore, nobody could test</p> <p>24 and confirm the existence of NDMA in</p>	<p style="text-align: right;">Page 93</p> <p>1 Q. Okay. Tell me what's</p> <p>2 incorrect. In July 2017, you've already</p> <p>3 agreed there was NDMA in valsartan, right?</p> <p>4 So that's correct?</p> <p>5 Let me ask it again.</p> <p>6 MR. SLATER: Dr. Shao, let me</p> <p>7 ask it again.</p> <p>8 Q. In July 2017, there was NDMA in</p> <p>9 valsartan manufactured with the zinc chloride</p> <p>10 process. That was a correct statement,</p> <p>11 right?</p> <p>12 MR. BERNARDO: I'm sorry, Adam.</p> <p>13 Can you repeat?</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Let me ask it differently. Let</p> <p>16 me ask it differently.</p> <p>17 In July of 2017, there was NDMA</p> <p>18 in the valsartan manufactured by ZHP. That's</p> <p>19 a correct statement, right?</p> <p>20 A. To the best of my recollection,</p> <p>21 I have already responded to that question</p> <p>22 just now.</p> <p>23 Q. In July of 2017, it was true</p> <p>24 that the NDMA in the valsartan was occurring</p>

<p style="text-align: right;">Page 94</p> <p>1 when the valsartan was quenched with sodium 2 nitrite during the manufacturing process. 3 That's a true, correct statement, right? 4 A. You cannot put it that way. I 5 don't think it is a correct statement. 6 Q. Well, how was the NDMA being 7 formed in the valsartan if it wasn't being 8 formed when the product was being quenched 9 with sodium nitrite? How was it happening if 10 that wasn't the way it was occurring? Please 11 tell me. 12 A. Let me go back to your previous 13 question. Maybe that was due to the 14 difference between Chinese and English, and 15 something must have lost -- might have been 16 lost in the translation. 17 I agree that there was NDMA in 18 the valsartan that we manufactured using the 19 zinc chloride-sodium nitrite manufacturing 20 process in 2017. 21 In fact, there was NDMA in 22 valsartan that was manufactured using the 23 same manufacturing process in 2011. That was 24 the result of our discovery in 2018.</p>	<p style="text-align: right;">Page 96</p> <p>1 BY MR. SLATER: 2 Q. Let's look at the e-mail. 3 Right underneath the little pictures there's 4 a paragraph that says, "In order to further 5 verify the structure of the impurity and its 6 formation mechanism, we plan to simulate the 7 quenching conditions and use the finished 8 Irbesartan product to react with NaNO2" -- 9 which is sodium nitrite -- "and HCl to 10 monitor the impurity produced by the 11 reaction, and then separate it for NMR for 12 final structural verification, while 13 simultaneously carrying out the confirmation 14 of the impurity by multi-stage MS," which 15 means mass spectrometry, correct? 16 And that's the method that's 17 used to identify NDMA in valsartan, correct? 18 MR. BERNARDO: Object to the 19 form. 20 BY MR. SLATER: 21 Q. Mass spectrometry, correct? 22 MR. BERNARDO: Object to the 23 form of the question. 24 THE WITNESS: That is</p>
<p style="text-align: right;">Page 95</p> <p>1 Q. And the true and correct fact 2 that there was NDMA in valsartan and it was 3 occurring when the valsartan was quenched 4 with sodium nitrite during the manufacturing 5 process, those true and correct facts were 6 made known to you and everybody that received 7 this e-mail in July of 2017, including but 8 not limited to Peng Dong, Linda Lin, and 9 Min Li, and yourself, correct? 10 MR. BERNARDO: Object to the 11 form of the question. 12 THE WITNESS: That is 13 incorrect. Actually, in July 2017, 14 people, including Jinsheng Lin and 15 others, including the people that I 16 just mentioned, such as Peng Dong, 17 Linda Lin, Min Li, and I, none of us 18 was aware of the existence of NDMA in 19 valsartan, while the reason being in 20 2017 we did not have the corresponding 21 analytical methods to test out NDMA; 22 therefore, nobody was aware of its 23 existence. 24 ///</p>	<p style="text-align: right;">Page 97</p> <p>1 completely incorrect. 2 BY MR. SLATER: 3 Q. Okay. So you don't use mass 4 spectrometry to identify NDMA in valsartan? 5 That's not how it was done? 6 MR. BERNARDO: Object to the 7 form of the question. 8 THE WITNESS: As I mentioned 9 earlier, in order to identify an 10 impurity, we have to find out the 11 identity of the impurity first, and 12 then develop analytical methods. 13 Over here the impurity was 14 referring to the impurity found during 15 the technical improvement of 16 irbesartan on page 1; therefore, the 17 followup work was referring to that 18 impurity, and the confirmation of the 19 structure of that impurity would be 20 done through mass spectrometry. 21 Once again, the impurity here 22 is regarding the one that was 23 discovered during the technical 24 improvement of irbesartan. He didn't</p>

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1 say anything about the confirmation of
2 the existence of NDMA. That is my
3 first point.
4 My second point is that at that
5 time we did not have the right
6 analytical method to identify NDMA in
7 valsartan; therefore, at that time
8 none of us was aware of the existence
9 of NDMA in valsartan.
10 BY MR. SLATER:
11 Q. As you said, the first thing
12 you need to do is figure out what impurity
13 you're looking for, and we know that it says
14 right in this e-mail there was NDMA in the
15 valsartan that occurred when it was quenched
16 with sodium nitrite.
17 So isn't the point that your
18 company already had mass spectrometry
19 available and had already figured out there
20 was NDMA in the valsartan before this e-mail
21 was ever written about this irbesartan
22 project? That's the point, isn't it?
23 MR. BERNARDO: Object to the
24 form of the question.

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1 THE WITNESS: Of course that
2 was not the point. If you look at the
3 whole body of this e-mail, I have to
4 say sure enough, this e-mail was so
5 poorly written, and you could not
6 simplify the e-mail by looking at only
7 one sentence. Even the paragraphs
8 written here were very confusing.
9 At that time, not only Jinsheng
10 Lin himself, even us, did not know
11 anything about the existence of NDMA
12 in valsartan. That was because there
13 was no analytical method would
14 identify NDMA in valsartan. That was
15 my first point.
16 My second point is that had we
17 known there was NDMA in valsartan at
18 that time, we would have taken the
19 same actions that we took in
20 June 2018.
21 MR. BERNARDO: Adam, when
22 you're at a point to take a break,
23 we've been going for about an hour and
24 20 minutes, and it's late.

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1 MR. SLATER: We can take a
2 break.
3 MR. BERNARDO: Okay. Let's do
4 that.
5 THE VIDEOGRAPHER: The time
6 right now is 11:26 a.m. We're off the
7 record.
8 (Whereupon, a recess was
9 taken.)
10 THE VIDEOGRAPHER: The time
11 right now is 11:44 a.m. We're back on
12 the record.
13 MR. BERNARDO: I just want to
14 point out that Mr. Slater and I were
15 just discussing the scheduling, and
16 it's ZHP's position that we've already
17 reduced the number of topics through
18 stipulations that we've provided by
19 two, so we're only remaining with
20 three topics. So surely we should be
21 able to get this done stopping at
22 midnight, which is reasonable tonight,
23 and doing the same thing tomorrow.
24 Both Ms. Brown and I, and I

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1 know Mr. Slater as well, are just
2 getting over COVID, and I really --
3 while I normally would be willing to
4 go later, I really don't want to
5 overdo it, and I would suggest we go
6 until midnight.
7 I'm not going to stop you in
8 the middle of a question; if it goes
9 like ten minutes or something over,
10 that's fine.
11 But we're just not comfortable,
12 for the reasons I just said, going
13 further. And we'll obviously work
14 with you to make sure we can get
15 through this deposition, but I don't
16 see why we can't complete it in
17 tonight and tomorrow night in the time
18 we just discussed.
19 MR. SLATER: All right. I'm
20 not going to -- probably -- probably
21 not too much benefit for us debating
22 too much over this, but my position is
23 we have a certain amount of time to
24 take this deposition. I'm not going

<p style="text-align: right;">Page 102</p> <p>1 to start recasting the time that we 2 had. 3 There was never any discussion 4 when we reached -- when you agreed to 5 admit to certain facts, there was no 6 discussion of limiting the time in a 7 deposition, nor would I ever have 8 agreed to that, nor was it ever 9 raised. So I think that that's a 10 little bit artificial. 11 Let's hope that we can do well 12 tonight and tomorrow, but we have over 13 12 hours of time by order. I argued 14 the issue, and the whole point was so 15 we wouldn't be put in a situation 16 where we would be running out of time 17 and start getting into double-time. 18 So I'm just saying we've only 19 been on the record for three hours and 20 49 minutes. I'm willing to keep 21 going, and maybe we should start 22 earlier tomorrow night. 23 MR. BERNARDO: Well, when we're 24 done, let's ask the witness, because</p>	<p style="text-align: right;">Page 104</p> <p>1 confusing and it was actually quite messy, 2 and it was very hard to understand what it 3 tried to say. 4 For this e-mail, the -- it 5 didn't say that it was aware of the valsartan 6 impurity at that time. So that's the first 7 thing I wanted to express. 8 My second point is that at that 9 time Dr. Lin did not become aware of the 10 existence of NDMA in valsartan. That's the 11 feedback he gave me through our 12 communication. 13 At that time, he was not 14 familiar with any impurity in valsartan. He 15 was not in charge of this product, so his 16 understanding of the impurity in valsartan 17 was only limited to this patent. 18 As to NDMA as an impurity in 19 valsartan, as in my prior statement, at that 20 time we needed a proper analytical method to 21 identify NDMA in valsartan. However, we 22 didn't have such analytical method; 23 therefore, neither did Jinsheng Lin or we had 24 any knowledge of the existence of NDMA in</p>
<p style="text-align: right;">Page 103</p> <p>1 it's obviously 7:00 a.m. her time. 2 MR. SLATER: She looks like an 3 early riser. 4 MR. BERNARDO: Sorry, I didn't 5 hear. 6 MR. SLATER: She looks like an 7 early riser. 8 MR. BERNARDO: We'll talk 9 afterwards. 10 MR. SLATER: Okay. 11 Are we back on? 12 THE VIDEOGRAPHER: We are on. 13 MR. SLATER: Okay. 14 BY MR. SLATER: 15 Q. Looking at the e-mail from 16 Jinsheng Lin, where he says there's NDMA in 17 the valsartan that occurs when it's quenched 18 with sodium nitrite, he doesn't refer to the 19 patent at all when he says that. The patent 20 comes later, at the end of the e-mail, in a 21 different context, correct? 22 A. That's incorrect. Actually, as 23 we have discussed in our prior testimony -- 24 in my prior testimony, this e-mail was very</p>	<p style="text-align: right;">Page 105</p> <p>1 valsartan. 2 Once again, this e-mail was 3 written in such a messy way, and that's the 4 reason why it was very confusing. 5 Q. Let's look at a few things that 6 are stated in this e-mail. 7 One of the things in the last 8 paragraph -- rephrase. 9 The last paragraph states in 10 part that the patent pointed out that the use 11 of sodium nitrite quenching will result in 12 the formation of N-nitroso impurities. 13 That's one of the things that 14 is stated, correct? 15 A. That is correct. That's what 16 the patent said. He was basically 17 summarizing what the patent said. 18 Q. He also says with regard to the 19 patent that this other company "used ZHP's 20 crude Valsartan in their LC-MS test and 21 detected this impurity," which was an 22 N-nitroso impurity, correct? 23 A. That's what the e-mail says. 24 However, through communication with Dr. Lin,</p>

<p style="text-align: right;">Page 106</p> <p>1 he told me that he heard that from a friend 2 of his. However, the other party did not 3 provide any chromatogram as well as data, so 4 he only recited or mentioned that he heard. 5 Q. He then says in this paragraph 6 that "This indicates" -- meaning what is 7 written in the patent -- "that other 8 companies have paid attention to the quality 9 problem very early on." 10 So he's referring to this 11 formation of N-nitroso impurities due to 12 sodium nitrite quenching as a quality 13 problem. That's what it says on the 14 document, correct? 15 A. Your statement is incorrect. 16 In the e-mail, he did refer to the 2013 17 patent. He also mentioned what he heard from 18 a friend of his regarding Impurity K. 19 But the e-mail also told us 20 that if, indeed, this Impurity K is a nitroso 21 compound, as it said, then it would become a 22 quality issue. And I agree with that. 23 Q. Who is this friend that 24 Jinsheng Lin spoke to? What's that person's</p>	<p style="text-align: right;">Page 108</p> <p>1 our product, then indeed this would be 2 regarded as a quality issue, a quality 3 problem. 4 Q. If you had detected NDMA in 5 valsartan, that would be a quality problem, 6 too, right? 7 A. Definitely. At that time we 8 didn't have the analytical method to detect 9 the NDMA in valsartan. Otherwise, we 10 wouldn't have been sitting here for this 11 deposition, right? 12 Q. He finishes that paragraph at 13 the end of this e-mail and says, "So leaders 14 please pay attention to this issue." Right? 15 That's what he said? 16 A. That is correct. 17 Q. So let's be clear. In this 18 e-mail, Jinsheng Lin said in an e-mail that 19 went to you, who -- you were the head of 20 quality at the time, is that correct? 21 A. I was the QA head at Chuannan 22 site, yes. 23 Q. It went to you; it went to 24 Min Li, who was the head of CEMAT; it went to</p>
<p style="text-align: right;">Page 107</p> <p>1 name? 2 A. He didn't disclose that 3 friend's name in our communication. After 4 all, it's part of the trade secret, you know, 5 in business, and I was shy of prying for such 6 information. 7 Nevertheless, even after our 8 company heard what he heard from the friend, 9 we paid attention to this issue. 10 Q. Dr. Lin referred to the use of 11 sodium nitrite quenching resulting from the 12 formation of N-nitroso impurities as a 13 quality problem, correct? 14 A. I don't quite get your 15 question. However, I'll try to respond. 16 In this e-mail, he did mention 17 the Impurity K referred to in the patent. If 18 this Impurity K is indeed a nitroso compound, 19 then we have to control this impurity. 20 That's from the perspective of FDA as well as 21 the perspective of GMP. We have to control 22 this impurity. 23 If, after confirmation, we have 24 confirmed or identified this Impurity K in</p>	<p style="text-align: right;">Page 109</p> <p>1 Peng Dong; it went to Linda Lin, the head of 2 regulatory, and some other people. 3 And in this e-mail, he said 4 that there was NDMA in valsartan that 5 occurred when it was quenched with sodium 6 nitrite. 7 He talked about a patent that 8 he read that said that the use of sodium 9 nitrite quenching will result in the 10 formation of N-nitroso impurities. 11 He pointed out that this would 12 be a quality problem, and he also said the 13 way to detect this impurity would be with 14 liquid chromatography-mass spectrometry, and 15 told the leaders to pay attention to this 16 issue. So all that information was there. 17 You and everyone on that e-mail 18 knew that you were quenching the valsartan 19 with sodium nitrite, yet it's your testimony 20 that nobody in response to this e-mail 21 actually said, Let's use the liquid 22 chromatography-mass spectrometry machine at 23 CEMAT -- which was an Agilent, A-G-I-L-E-N-T, 24 6100 single quad LC-MS machine -- and let's</p>

<p style="text-align: right;">Page 110</p> <p>1 try to identify whether there's nitrosamines 2 in our valsartan. 3 Do I have that correct? 4 MR. BERNARDO: Object to the 5 form of the question. 6 THE WITNESS: That's completely 7 incorrect. Look at the title of this 8 e-mail. It was about the impurity 9 that generated from the sodium azide 10 quenching in the technical improvement 11 of irbesartan. 12 For this impurity, this e-mail 13 was actually the investigation report. 14 It is all about irbesartan. 15 So while he was searching for 16 this nitroso impurity, he found this 17 patent regarding valsartan, which 18 mentioned Impurity K. And he was 19 trying to make a comparison between 20 that impurity from irbesartan and 21 Impurity K as well as NDMA in 22 toxicology. 23 In the end of the e-mail, he 24 did mention that could be a quality</p>	<p style="text-align: right;">Page 112</p> <p>1 for that impurity, simply because we 2 were not aware of that impurity, not 3 until June 2018 when Novartis made the 4 complaint. And the company was paying 5 full attention to that. 6 Not only did we develop the 7 analytical method to detect that 8 impurity; we also reported that to 9 FDA, among many other actions we took. 10 Had we known the existence of 11 NDMA in valsartan in 2017, we would 12 have done the same thing that we did 13 in 2018. 14 So as you can see here, this 15 report is about the investigation of 16 an impurity in this small-scale 17 technical improvement of irbesartan. 18 And how could we then expand that to 19 an already commercialized product, 20 valsartan, for the suspicion that 21 there might be NDMA in it? 22 So out of common sense, this 23 doesn't sound reasonable. Once again, 24 at that time we were not aware of the</p>
<p style="text-align: right;">Page 111</p> <p>1 issue, because for valsartan that 2 could be Impurity K, which was already 3 found by an analysis done by other 4 companies. So he asked all the 5 leaders to pay attention, which we 6 did. 7 I don't know why you interpret 8 the e-mail this way. As in the large 9 volume of discussion we had before, in 10 2017 Jinsheng Lin, Min Li, or any of 11 us did not know the existence of NDMA 12 in valsartan. 13 There are so many reasons why 14 we were not aware of that, one of them 15 being that we did not have the 16 analytical method to identify and 17 detect the NDMA in valsartan. We were 18 not aware of such thing, so how could 19 we come up with the analytical method 20 such as LC-MS for any unknown 21 impurity? How could we make up any 22 analytical method for that? 23 So we didn't know what to do. 24 We didn't know what method to develop</p>	<p style="text-align: right;">Page 113</p> <p>1 existence of NDMA in valsartan. 2 BY MR. SLATER: 3 Q. The e-mail says that the use of 4 sodium nitrite quenching in valsartan will 5 result in the formation of N-nitroso 6 impurities. 7 So even accepting everything 8 you said about what ZHP didn't know, as of 9 the date of this e-mail, your company was on 10 notice that the sodium nitrite quenching of 11 any of its sartans needed to be investigated 12 and testing needed to be done to see if 13 nitrosamines were being formed, right? 14 Nothing was done, correct? 15 According to you, nothing was done? 16 MR. BERNARDO: Objection. Let 17 her answer the first question before 18 you ask the second, please. 19 THE WITNESS: What's the first 20 question? Your question was super 21 long. 22 BY MR. SLATER: 23 Q. I'm not asking the question 24 again. You heard the question; you can</p>

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1 answer it.
 2 Do you want me to ask a new
 3 question? I'll ask a new question. It was
 4 objected to; I'm happy to.
 5 So here's the first thing.
 6 After this e-mail was sent, no testing was
 7 done of any of your sartans to determine
 8 whether N-nitroso compounds were being formed
 9 due to the sodium nitrite quenching, is that
 10 your testimony?
 11 MR. BERNARDO: Object to the
 12 form of the question.
 13 THE WITNESS: It's not correct.
 14 You cannot put it in that way.
 15 Over here we talked about the
 16 Impurity K, because the patent
 17 mentioned Impurity K. And also other
 18 companies found Impurity K in the
 19 analysis of our crude products.
 20 We actually care about the
 21 impurity in our finished products;
 22 therefore, after communication I found
 23 that not only Jinsheng Lin, but also
 24 Peng Dong, did analysis of Impurity K

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1 and couldn't find any Impurity K.
 2 So we did pay attention to this
 3 issue and took actions. You cannot
 4 say we never conducted any testing.
 5 BY MR. SLATER:
 6 Q. You're saying that Jinsheng Lin
 7 and Peng Dong in 2017 tested valsartan to see
 8 if there was Impurity K in it?
 9 A. It went like this. During the
 10 communication with Jinsheng Lin, he told me
 11 he did conduct analysis of Impurity K in
 12 2017.
 13 Likewise, I also communicated
 14 with Peng Dong, and he also conducted an
 15 analysis regarding Impurity K in our product.
 16 And he also received the feedback from CEMAT
 17 that CEMAT did not find any Impurity K in our
 18 product.
 19 Q. What CEMAT did find was NDMA in
 20 the valsartan, and that's why Jinsheng Lin
 21 said it in his e-mail, that there's NDMA in
 22 the valsartan that's caused when it's
 23 quenched with sodium nitrite.
 24 That is what was found, right?

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1 MR. BERNARDO: Object to the
 2 form of the question.
 3 Characterization of the prior
 4 testimony.
 5 THE WITNESS: That's completely
 6 incorrect.
 7 As I stated in my prior
 8 testimony, Jinsheng Lin or any of the
 9 other people on this e-mail was not
 10 aware of the existence of NDMA in
 11 valsartan, because at that time there
 12 was no such analytical method to
 13 identify NDMA in valsartan. So your
 14 statement is completely incorrect.
 15 BY MR. SLATER:
 16 Q. You're -- rephrase.
 17 So you're testifying that when
 18 Jinsheng Lin said there was NDMA in
 19 valsartan, he said that for no reason, and it
 20 was just a complete coincidence and lucky
 21 guess?
 22 Is that your testimony?
 23 MR. BERNARDO: Object to the
 24 form of the question.

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1 THE WITNESS: Your statement is
 2 completely incorrect, as I stated in
 3 my prior testimony.
 4 At that time Jinsheng Lin was
 5 not aware of the existence of NDMA in
 6 valsartan. His understanding of NDMA
 7 in valsartan was only limited to that
 8 patent.
 9 I also stated that this e-mail,
 10 in terms of what it tried to state,
 11 was written in such a messy and
 12 ambiguous way.
 13 And in this e-mail, he was
 14 trying to make a comparison between
 15 NDMA and that impurity he found in
 16 toxicology. So the e-mail did not
 17 acknowledge that he already had the
 18 awareness of NDMA in valsartan. And
 19 none of us did, the reason being there
 20 was no analytical method to identify
 21 such an impurity.
 22 Without such an analytical
 23 method to identify the impurity in the
 24 testing, how can we come up with such

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1 knowledge? Therefore, I believe your
 2 statement is completely incorrect.
 3 In order to fully understand
 4 this e-mail, I also mentioned before
 5 that you need to read the context of
 6 the e-mail or the entirety of this
 7 e-mail, as well as the attachment to
 8 it.
 9 BY MR. SLATER:
 10 Q. The patent does not mention
 11 NDMA, correct?
 12 A. That is correct. The patent
 13 did not mention NDMA in its entirety.
 14 Q. Jinsheng Lin did reference NDMA
 15 in valsartan in his e-mail, correct?
 16 A. I already mentioned that in
 17 terms of the reference of NDMA, at the time
 18 he was only trying to make a comparison in
 19 toxicology between NDMA and the impurity he
 20 found regarding the irbesartan.
 21 The patent did not mention
 22 NDMA. However, the patent mentioned that
 23 when valsartan was quenched with sodium
 24 nitrite, there was an -- an impurity came.

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1 That is the evidence that at
 2 that time the whole industry, ZHP, or
 3 Jinsheng Lin did not have the awareness of
 4 NDMA in valsartan. Otherwise, the patent
 5 would have mentioned NDMA instead of
 6 Impurity K.
 7 Q. When you say that there was not
 8 an analytical method to identify NDMA in the
 9 valsartan, you're not saying that it wasn't
 10 technologically feasible to do it, right?
 11 You're not claiming that there was no such
 12 method in the world to do that, are you?
 13 A. As I mentioned before, when you
 14 try to develop an analytical method for a
 15 specific impurity, you have to do that
 16 development regarding that impurity.
 17 I listed two FDA announcements
 18 or documents. Judging from the content of
 19 such documents, you could tell that first you
 20 have to be aware of such an impurity. Then
 21 you would develop an analytical method
 22 targeting that impurity.
 23 Q. And that was technologically
 24 feasible in 2011 through 2018, right?

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1 MR. BERNARDO: Object to the
 2 form of the question.
 3 THE WITNESS: I don't know what
 4 you mean by "technologically
 5 feasible." Can you be more specific?
 6 BY MR. SLATER:
 7 Q. The technology and the
 8 scientific knowledge existed so that if one
 9 at ZHP wanted to develop a method to try to
 10 identify NDMA in valsartan, that could be
 11 done, correct?
 12 MR. BERNARDO: Object to the
 13 form of the question.
 14 THE WITNESS: Had we known
 15 prior to June 2018 that there was an
 16 impurity called NDMA, I believe my
 17 company would have been capable of
 18 developing such an analytical method
 19 for this impurity, just like what we
 20 did when we became aware of such an
 21 impurity in June 2018.
 22 MR. BERNARDO: Adam, I'm trying
 23 to be cooperative. We went a
 24 half-hour longer than we had

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1 anticipated. And if we can end it
 2 here, I'm happy to go off the record
 3 and ask Ms. Ge if she's willing to
 4 start early tomorrow as well. But I'd
 5 like to stop here.
 6 MR. SLATER: Well, I'm going to
 7 be a gentleman and I'm not going to
 8 argue with you. I've already told you
 9 how I feel about it. I'm prepared to
 10 keep going, but I understand your
 11 position, and I'm going to try to be
 12 optimistic that despite my
 13 disappointment in not getting to go
 14 into the deep of night, that we'll be
 15 able to finish this deposition
 16 tomorrow night and not ruin
 17 everybody's Friday night before
 18 Memorial Day.
 19 MR. BERNARDO: I would point
 20 out we are in the deep of the night,
 21 but other than that, I appreciate
 22 that.
 23 Why don't we go off the record
 24 and see if Ms. Ge is willing to start

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1 earlier tomorrow.
 2 THE VIDEOGRAPHER: The time
 3 right now is 12:32 p.m. We're off the
 4 record.
 5 (Whereupon, the deposition was
 6 adjourned.)
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 2 **CERTIFICATE**
 3 I, MAUREEN O'CONNOR
 4 POLLARD, Registered Diplomat
 5 Reporter, Realtime Systems
 6 Administrator, and Certified Shorthand
 7 Reporter, do hereby certify that prior
 8 to the commencement of the
 9 examination, JUCAI GE, was remotely
 10 duly identified and sworn by me to
 11 testify to the truth, the whole truth,
 12 and nothing but the truth.
 13 I DO FURTHER CERTIFY that
 14 the foregoing is a verbatim transcript
 15 of the testimony as taken
 16 stenographically by and before me at
 17 the time, place, and on the date
 18 hereinbefore set forth, to the best of
 19 my ability.
 20 I DO FURTHER CERTIFY that
 21 I am neither a relative nor employee
 22 nor attorney nor counsel of any of the
 23 parties to this action, and that I am
 24 neither a relative nor employee of
 such attorney or counsel, and that I
 am not financially interested in the
 action.

 MAUREEN O'CONNOR POLLARD
 NCRA Registered Diplomat Reporter
 Realtime Systems Administrator
 Certified Shorthand Reporter
 Notary Public
 Dated: June 2, 2022

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1 **INSTRUCTIONS TO WITNESS**
 2
 3 Please read your deposition over
 4 carefully and make any necessary corrections.
 5 You should state the reason in the
 6 appropriate space on the errata sheet for any
 7 corrections that are made.
 8 After doing so, please sign the
 9 errata sheet and date it. It will be
 10 attached to your deposition.
 11 It is imperative that you return
 12 the original errata sheet to the deposing
 13 attorney within thirty (30) days of receipt
 14 of the deposition transcript by you. If you
 15 fail to do so, the deposition transcript may
 16 be deemed to be accurate and may be used in
 17 court.
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1 -----
 2 **ERRATA**
 3 -----
 4 **PAGE LINE CHANGE**
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ACKNOWLEDGMENT OF DEPONENT

I, _____, do
Hereby certify that I have read the foregoing
pages, and that the same is a correct
transcription of the answers given by me to
the questions therein propounded, except for
the corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

WITNESS NAME DATE

Subscribed and sworn
To before me this
_____ day of _____, 20____.

My commission expires: _____

Notary Public

LAWYER'S NOTES

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